

Resolution Table for second round of public comments

SUMMARY OF SUBMISSIONS AND RESPONSES

Title of Document: Code for Radiation Protection in Planned Exposure Situations (PEC)

Period of public comment – Second round – September 2016

#	SUBMITTER	COMMENT	RESPONSE
1.	Bruce Hocking Member RHC	<p>I think it would be more internally consistent with 3.2.2 if an occupationally exposed person was defined as follows.</p> <p style="padding-left: 40px;">Persons potentially exposed to radiation from sources within the practice that are required by or directly related to their work</p>	<p>The definition given in the Glossary of the PEC is the same as that given in GSR Part 3. Further, occupational exposure is intended to apply to any person who might be exposed to radiation in their workplace even though they do not directly work with radiation.</p>
2.	ARPS	<p>General Comments</p> <p>In general, the draft Code is acceptable, assuming that it will be supported by Safety Guides or Recommendations for specific practice types. However, it is not clear from the information provided:</p> <ul style="list-style-type: none"> • which documents within the existing radiation protection series (RPS) range are intended to be replaced by the draft Code, and • what will happen with the existing Safety Guides which are associated with these Codes. <p>It has been noted that, in the case of the Medical Exposure Code, a gap analysis was conducted to illustrate that there is no significant difference between the existing RPS documents and the new Medical Exposure Code. In this case, are there gaps in the existing RPS documents to support the development of a draft Planned Exposure Code?</p> <p>There does not seem to be any indication of what should be done in situations involving both radiological and non-radiological hazards. Such situations should be considered, because of the possibility that, in dealing with a radiological hazard, an individual may be exposed to other hazards.</p>	<p>The Code, together with RPS F-1, supersedes the <i>Recommendations for Limiting Exposure to Ionizing Radiation (1995)</i> and <i>National Standard for Limiting Occupational Exposure to Ionizing Radiation (republished 2002) (RPS1)</i>, as noted in the Foreword. For the time being, it will sit in ARPANSA’s Radiation Protection Series in the same way as RPS1 has. Any decision to remove/revoke/rescind other Codes or Safety Guides will be made in the future.</p> <p>It will be important for ARPANSA and the RHC to engage with key bodies such as ARPS to understand the practical implications for users of Codes and Safety Guides.</p> <p>The proposed Code is an overarching radiation protection document and is intended to take the place of RPS1. Any ‘gaps’ are expected to be filled by later publications in the Radiation Protection Series.</p> <p>It is correct that the document does not address situations involving both radiological and non-radiological hazards, however this is an issue that is already faced by radiation safety practitioners. The justification and optimisation aspects of radiation protection need to take into account radiation in the context of other hazards. It is however particularly relevant in</p>

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		<p>There are several instances in the document where the meaning of words that are in common usage is changed without careful (precise) definition of the meaning of these words in a radiological context. This issue is discussed in the specific comments below.</p> <p>Specific comments:</p> <p>Foreword <i>Second paragraph, Third line</i></p> <p>The use of the term “planned activity” is confusing. Here the term refers to carrying out an action. However, in radiation protection the term activity is used to denote the number of nuclear transformations per second. It is used in that sense in this document (e.g. lines 254, 436, 437, 443, 527, 528, 664).</p> <p style="text-align: center;">Suggest replacing “planned activity” by “planned operation”</p> <p><i>Fifth paragraph, Third line</i></p> <p>See previous comment.</p> <p>What planned activity is referred to here?</p> <p style="text-align: center;">The second sentence needs to be rewritten in an unambiguous form.</p> <p>1.3 Purpose <i>Line 38</i></p> <p>“conducts an activity” refers to carrying out an action – the term activity has a different connotation in radiation practice (nuclear transformations per second)</p> <p style="text-align: center;">Suggest replacing “conducts an activity” by “carries out an operation”</p> <p>1.4 Scope <i>Line 49</i></p> <p>In general, radiation exposure isn’t expected to occur during the production and supply of devices that generate radiation, rather during their operation during</p>	<p>emergency exposure situations, as there may well be risk to life or health, and as such there may be value in considering how the emergency exposures guide addresses this point.</p> <p>Noted.</p> <p>Changed to ‘... planned operation of a radiation source or facility ...’ and a definition adapted from GRS Part 3 added to the Glossary.</p> <p>Amended as above.</p> <p>Done.</p> <p>Noted. ‘testing’ added.</p>

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		<p>testing or installation.</p> <p>The Code doesn't appear to be applicable to production and supply except for activities that would be covered by Use of Radiation.</p> <p><i>Lines 68-69</i></p> <p>Again, what is meant by "planned activity" in this context?</p> <p style="padding-left: 40px;">The sentence needs to be rewritten in an unambiguous form.</p> <p><i>Line 70</i></p> <p>Suggest using the defined term "Medical Exposure"</p> <p style="padding-left: 40px;">Change (c) to Medical Exposure.</p> <p>2. Objectives</p> <p><i>Line 107</i></p> <p style="padding-left: 40px;">Suggest replacing "planned activity" by "planned operation"</p> <p><i>Line 116</i></p> <p>The word "natural" is used in several different ways throughout the document – what is meant by "natural environment"? Is it that part of the environment that results from natural processes?</p> <p>The common usage of the term natural environment implies that part of the environment that has not been affected by human action. This is consistent with the definition of natural in the Oxford Dictionary.</p> <p style="padding-left: 40px;">"natural environment" needs to be defined in the Glossary</p> <p><i>Line 117</i></p> <p>Both "dose" and "dose limit" are defined in the Glossary. However, this line is the first reference to both "dose" and "dose limit".</p> <p style="padding-left: 40px;">The text needs to be modified for consistency with the statement in lines 80-82.</p> <p>2.1 Justification</p> <p><i>Line 131</i></p> <p>The use of the term "increase in activity" in this context really means "increase in</p>	<p>Changed to '... planned operation of a radiation source or facility'.</p> <p>Agreed.</p> <p>Amended to remove 'activity' and introduce 'facility'.</p> <p>'natural' removed. 'Environment' is already defined.</p> <p>'dose limit' bolded.</p> <p>Done.</p>

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		<p>radionuclide concentration”</p> <p style="text-align: center;">Suggest replacing “increase in activity” by “increase in radionuclide concentration” for clarification</p> <p><i>Line 136</i></p> <p>See previous comment</p> <p style="text-align: center;">Suggest replacing “increase in activity” by “increase in radionuclide concentration in commodities or in total activity in consumer products” for clarification</p> <p><i>Line 136</i></p> <p>The term “activation” is not defined</p> <p style="text-align: center;">This term needs to be defined in the Glossary</p> <p><i>Lines 147-150</i></p> <p>Other Government agencies may need to be involved in decisions of this type</p> <p style="text-align: center;">Text may need to be modified</p> <p><i>Lines 151-153</i></p> <p>Other Government agencies may need to be involved in decisions of this type</p> <p style="text-align: center;">Text may need to be modified</p> <p><i>Line 153</i></p> <p>Should there be a qualifying word on “Public exposure”? E.g. minimal public exposure.</p> <p>Otherwise, this paragraph appears to say exposing the public gives rise to public exposure.</p> <p>2.2 Optimisation</p> <p><i>Line 157</i></p> <p style="text-align: center;">Suggest replacing “a tool” by “an operational tool”</p> <p><i>Line 159</i></p>	<p>Done</p> <p>Done. GSR Part 3 definition added to the Glossary.</p> <p>Jurisdictions are able to determine and specify relevant regulatory authorities for the purposes of each provision of the Code, and this need not be the same agency throughout. No change.</p> <p>transcription error</p> <p>This statement does not seek to control the exposure, rather it identifies that exposure for these purposes is considered to be exposure of the public (rather than medical or occupational) and thus that relevant limits apply. It is included in this section for completeness.</p> <p>Done.</p> <p>Removed, ‘facility’ added for consistency with above.</p> <p>Done.</p>

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		<p>Suggest replacing “activity” by “operation”</p> <p><i>Line 160</i></p> <p>Poor grammar</p> <p>Suggest replacing “prevent dose limits to be exceeded” by “prevent dose limits from being exceeded”</p> <p><i>Line 166</i></p> <p>It is the Responsible Person who is responsible for the establishment of dose constraints – see Section 3.1.13</p> <p>Suggest replacing “the regulatory body ensures the establishment or approval of dose constraints” by “the operator should establish, and the regulatory authority approve, dose constraints”</p> <p><i>Line 168</i></p> <p>See previous comments regarding the use of the term “activity”</p> <p>Suggest replacing “activity” by “operation”</p> <p><i>Line 179, 180</i></p> <p>“Potential Exposure” is in bold, but there is no corresponding definition in the Glossary. The concept of potential exposure outlined in the preceding sentence is important.</p> <p>Add a definition for Potential Exposure</p> <p>2.5 The Role of the RP</p> <p><i>Line 254</i></p> <p>The use of the term “activity” here is unambiguous, provided “activity” is defined in the Glossary</p> <p>Define “activity” in the Glossary</p> <p>3. Safety Requirements</p> <p><i>Line 261</i></p> <p>The Occupational Exposure section is 3.2.</p> <p>Change “Occupational exposure (section 3.1)” to “Occupational exposure (section</p>	<p>No, consistent with IAEA GSR Part 3, 3.1.13 states that the RP must adopt appropriate dose constraints into their RMP. It does not state who establishes or approves them. The ‘or’ here allows either to establish them.</p> <p>Removed and ‘facility’ inserted for consistency with above.</p> <p>Done – GSR Part 3 definition added to Glossary</p> <p>Done – GSR Part 3 definition added to Glossary</p> <p>Done</p> <p>True, but section 2.5 is essentially information. Chapter 3</p>

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		<p data-bbox="1323 140 1384 164">3.2)”</p> <p data-bbox="465 193 618 217"><i>Lines 260-262</i></p> <p data-bbox="465 245 1240 269">Some of these responsibilities have already been outlined in Section 2.5</p> <p data-bbox="909 298 1379 322">The text should be modified for consistency</p> <p data-bbox="465 351 560 375"><i>Line 264</i></p> <p data-bbox="465 403 837 427">See comment re lines 159 and 168</p> <p data-bbox="920 456 1379 480">Suggest replacing “activity” by “operation”</p> <p data-bbox="465 509 560 533"><i>Line 265</i></p> <p data-bbox="465 561 647 585">Same as line 264</p> <p data-bbox="465 614 763 636">3.1 General Requirements</p> <p data-bbox="465 665 831 689"><i>Line 323 to 326, and clause 3.1.11</i></p> <p data-bbox="465 718 1144 742">The uses listed in clause 3.1.10(b) are to be “within a practice”.</p> <p data-bbox="465 770 1196 794">Clause 3.1.11 applies to “Any person” – both corporate and natural.</p> <p data-bbox="465 823 1379 943">In general, users of radiation are authorised by holding a licence. Clause 3.1.11 suggests that a licensed user (“any person”) would need to notify the relevant regulatory authority (RRA) that they intended to use/operate a radiation source within a different practice every time they changed employer.</p> <p data-bbox="465 971 1379 1075">It is not clear that a user of radiation needs to notify a RELEVANT REGULATORY AUTHORITY of their intention to use. Notification might be better covered by the practice owner under 3.1.10(a) rather than their employees.</p> <p data-bbox="808 1104 1379 1128">Reconsider the requirement to be “within a practice”</p> <p data-bbox="465 1157 560 1181"><i>Line 326</i></p> <p data-bbox="465 1209 1294 1233">It is assumed that “source” in this case means “Radiation Source” as defined.</p> <p data-bbox="465 1262 618 1286"><i>Lines 405-406</i></p> <p data-bbox="465 1315 1211 1339">Should a radioactive source also be stored appropriately for security?</p> <p data-bbox="981 1367 1379 1391">Replace “protection” with “security”.</p> <p data-bbox="465 1420 560 1444"><i>Line 421</i></p>	<p data-bbox="1413 140 1827 164">contains the mandatory requirements.</p> <p data-bbox="1413 336 1610 360">‘Activity’ removed.</p> <p data-bbox="1413 437 1603 461">Activity’ removed.</p> <p data-bbox="1413 600 1711 624">‘within a practice’ removed.</p> <p data-bbox="1413 636 1496 660">Correct.</p> <p data-bbox="1413 699 1924 722">Removal of ‘within a practice’ should cover this.</p> <p data-bbox="1413 1091 1599 1115">‘radiation’ added.</p> <p data-bbox="1413 1192 2107 1279">‘protection and safety’ has a defined meaning in the Glossary (as taken from GSR Part 3). Storage for security purposes come under RPS11 at this time.</p> <p data-bbox="1413 1355 1632 1378">(iii) would cover this.</p>

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		<p>Medical diagnostic equipment might be used to detect objects concealed in the body. Should there be a requirement to conform to medical standards as well? Or would this be covered by point (iii)?</p> <p><i>Lines 411-426</i></p> <p>See the earlier comments on lines 147-153</p> <p>3.2 Requirements for Occ Exposure</p> <p><i>Lines 428-432</i></p> <p>The text appears to imply that the requirements for occupational planned exposure situations should also be applied to emergency and existing exposure situations as required.</p> <p>This is confusing, as it implies that the latter situations can in some circumstances be treated as planned exposure situations – this is not consistent with the definitions of planned, existing and emergency exposure situations.</p> <p><i>Line 433</i></p> <p>What is meant by “natural source”?</p> <p>Is it a material containing radionuclides that has achieved its present configuration without human intervention (i.e. as a result of natural processes), or is it a material that contains naturally occurring radionuclides (i.e. those from the U-238, U-235 and Th-232 decay chains, or K-40)?</p> <p>Common usage of the term natural source is a source that exists in its present form as a result of natural processes, i.e. no human intervention. This is simple and unambiguous.</p> <p><i>Lines 433-442</i></p> <p>The problems associated with this approach were pointed out at the recent ARPS conference in Adelaide (O’Brien, 2016) [<i>NORM and NORM Management</i>]. In particular this approach leads to inconsistencies, because it implicitly assumes that the exposure scenarios are the same in all situations. This assumption is clearly not valid.</p> <p style="padding-left: 40px;">This issue needs to be addressed to avoid future problems, and to ensure a self-consistent, defensible approach. This can best be done by requiring that a</p>	<p>Yes, but the relevant regulatory authority has the say over radiation protection.</p> <p>The ‘as required’ should cover this.</p> <p>Definition of ‘natural source’ from GSR Part 3 added to Glossary.</p> <p>Noted. This is taken directly from GSR Part 3, requirement 5.</p>

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		<p>dose/impact assessment be carried out in all cases.</p> <p><i>Line 494</i></p> <p>What is meant by “the characteristics of the occupationally exposed persons”?</p> <p><i>Lines 524-531</i></p> <p>Same as previous comment on lines 433-442</p> <p>Schedule A</p> <p><i>Line 583</i></p> <p>The dose limit for the lens of the eye in GSR part 3, and as recommended by the ICRP is averaged over 5 years: “An equivalent dose to the lens of the eye of 20 mSv per year averaged over five consecutive years (100 mSv in 5 years) and of 50 mSv in any single year;”</p> <p>Change to adopt the lens of the eye dose limit averaged over 5 years.</p> <p><i>Line 583</i></p> <p>GSR part 3 has lower dose limits for people aged between 16 and 18.</p> <p>Appendix 2</p> <p><i>Lines 678-686</i></p> <p>Why would dose constraints not also be applicable in some existing exposure situations, e.g. mining operations, particularly underground operations?</p> <p><i>Line 721</i></p> <p>The reference to “natural processes” uses the term in its commonly accepted sense, but is not consistent with the use of the word natural in the term “natural sources” – see comment on line 433</p> <p>The ambiguities and inconsistencies need to be addressed.</p> <p><i>Line 729</i></p> <p>Editing required</p> <p>Replace “ ” by “.” in the equation</p>	<p>This was taken from RPS1. However, it has been changed to ‘consistent with the training needs of ...’.</p> <p>Noted. This is taken directly from GSR Part 3, requirement 5.</p> <p>Done – Schedule A amended accordingly.</p> <p>Noted. This was not considered necessary at this time.</p> <p>The requirements for planned exposure situations apply to mining (1.4(f)). Dose constraints are not applicable to existing exposure situations.</p> <p>‘Natural sources’ now defined. Both ‘natural sources’ and ‘environment’ have been taken from GSR Part 3.</p> <p>Either works here to indicate multiplication.</p> <p>This is from GSR Part 3 and the revised medical code will therefore (in time) also adopt the same definition.</p>

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3	Dr Rick Olive President Australian Dental Association	<p><i>Line 780</i></p> <p>Align this definition with the Medical Exposure code RPS C-3. The planned exposure code has the better definition.</p> <p><i>Lines 803-804 and 810</i></p> <p>Same as line 264</p> <p style="text-align: center;">Suggest replacing “activity” by “operation”</p> <p><i>Lines 814 and 872</i></p> <p>Is there any difference between “Protection and Safety” and “Safety” as defined? Is there a need for 2 terms that are roughly the same?</p> <p style="text-align: center;">Remove Protection and Safety, and use Safety for simplicity.</p> <p><i>Line 900 References</i></p> <p>The text of this Code refers to a separate Code for Medical Exposure. Line 615. Similarly for emergency exposure.</p> <p style="text-align: center;">Consider inclusion of the medical exposure code as a reference. Similarly for emergency exposure</p> <p>The ADA notes this draft has considered our 5 June 2015 submission and, in response, has now included clause (f) and a definition of an ‘exemption’ that has been now inserted (underlined below):</p> <p><i>Line 66</i></p> <p>This Code does not apply to:</p> <ul style="list-style-type: none"> (a) existing exposure situations (b) emergency exposure situations, except for emergency situations arising from the planned activity (c) patients undergoing medical diagnosis or therapy involving radiation (d) participants in research involving exposure of human volunteers to radiation (e) non-occupational exposure received as a consequence of assisting an exposed 	<p>These are the definitions used in GSR Part 3, and ARPANSA and the Radiation Health Committee have adopted the principle, where it does not compromise radiation protection outcomes or is inconsistent with Australian legislation, to seek consistency with IAEA definitions. The changes work in the body of the text but not in the definitions.</p> <p>Both ‘protections and safety’ and ‘safety’ are defined and are directly adopted from GSR Part 3.</p> <p>These are still in draft and are some way off being published.</p>

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		<p>patient</p> <p>(f) <u>dealings with material below the exemption limit prescribed by the relevant regulatory authority</u></p> <p>(g) dealings with bulk amounts¹ of material below the clearance level prescribed by the relevant regulatory authority.</p> <p>Exemption (Glossary: Page 27)</p> <p>The determination by the relevant regulatory authority that a source or practice need not be subject to some or all aspects of regulatory control on the basis that the exposure and the potential exposure due to the source or practice are too small to warrant the application of those aspects or that this is the optimum option for protection irrespective of the actual level of the doses or risks.</p> <p>The amendments above appropriately reflect the existing practice that sees many dental practices exempt from the obligation to use personal radiation monitors after having provided evidence that the dose levels in their practices are far below the maximum permissible levels. The amendments above are now consistent with the <i>Recommendation for Limiting Exposure to Ionizing Radiation (1995)</i> and the <i>National Standard for Limiting Occupation Exposure to Ionizing (RPS1)</i>. The ADA notes that the current <i>Radiation Protection in Dentistry Code of Practice and Safety Guide (2005)</i> recommends the use of personal monitoring but does not make it mandatory. This was based upon RPS1, which states:</p> <p style="padding-left: 40px;"><i>While group or area monitoring strategies may be sufficient when assessed doses are well below the dose limits, personal monitoring should be undertaken as far as is practicable when doses may be a significant fraction of the limits.</i></p> <p>In the absence of evidence to the contrary, the ADA's view is that the level of risk, compared to the probability of the risk of inappropriate exposure to occur, is minimal. Also, over the past decade the level of risk associated with dental radiography has reduced as there has been very widespread conversion to digital radiography throughout dentistry with substantial reductions in exposure dosages.</p> <p>While this is the ADA's general position, in dental practices cone beam machines may need to be monitored. The ADA draws attention to the case in Queensland where monitoring badges are used for a specified period of time and practitioners</p>	<p>The ADA's comments are acknowledged. ARPANSA notes that the Planned Exposure Code as framed allows for a graded approach, and exemption by the relevant regulatory authority from certain requirements, and should see no change to existing requirements.</p>

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4	Neha Kodwani WHS Branch ANU	<p>are permitted to stop using them if no adverse readings are recorded.</p> <p>The Code could be significantly improved by including the word ionising. The Code is about planned exposure to ionising radiation and supersedes publications having that purpose:- <i>Recommendations for Limiting Exposure to Ionising Radiation (1995)</i> and <i>National Standard for Limiting Occupational Exposure to Ionising Radiation (2002)</i>.</p> <p>The Code has its basis in the Safety Requirements of the International Atomic Energy Agency (IAEA); <i>Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards</i>. In contrast to ARPANSA, the IAEA has no statutory responsibilities in relation to non-ionising radiation. I would suggest that (further) consideration be given to amending the title of the new Code to Ionising Radiation Protection in Planned Exposure Situations.</p> <p>Section 1.4 (Line 73):</p> <p>There should be a clear explanation of the Exemption limits to be used here (storage, disposal or handling, etc.), including definitions and an explanation of what is intended. It should be better phrased within the context.</p> <p>Section 3 (Line 261):</p> <p>Reference to occupational exposure should be section 3.2 instead of 3.1.</p> <p>Section 3.1.8 (Line 314):</p> <p>I request that “a qualified expert” be changed to “a qualified expert or expert panel”.</p> <p>Section 3.1.10 (lines 323- 326):</p> <p>I believe this section requires substantial modification. There should be a clear explanation of all the terms described within the context. How is a source being defined here? Is it a radiation source (sealed/unsealed) or source of radiation (ionising X-Ray apparatus)? In our University environment, where we continuously develop, modify, improve, and consequently maintain our equipment as part of our research programs, it is unrealistic to submit a notification for approval by the regulatory authority prior to commencing most of the prescribed terms. For example, repair work on our accelerators during the middle of an international collaborative experiment, that would have no impact on radiation levels, should not require that we seek authority to repair the equipment.</p>	<p>That this proposed Code applies to ionising radiation is explicitly stated in Section 1.3 Purpose. It is also stated in the Glossary definition of radiation that it only refers to ionising radiation in this Code.</p> <p>These are within the province of the relevant regulatory authority and are generally included in the National Directory.</p> <p>Done.</p> <p>Noted. The Code does not preclude the use of expert panels, but the Radiation Health Committee considers that a qualified expert is required.</p> <p>An important aspect of a regulatory framework is the requirement for certain practices to be subject to authorisation. Enforceable (legal) definition of these practices is necessarily with jurisdictions, and relevant regulatory authorities will have final say over which of the items requires authorisation. Where there is doubt, or where exemption from authorisation is appropriate, the regulator is able to provide clarification or exemption. From the proponent’s perspective, they should engage with their regulator to clarify authorisation requirements. In this example, the original authorisation should include the scope of the authorisation including repair to</p>

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5	ANSTO	<p>Section 3.3.3: I believe the cost of a monitoring program would not be commensurate with the benefits in our case. In the past, there have been only rare incidents of elevated effective doses to radiation workers within the University. Taking in consideration our history, the operational practices and substantial shielding infrastructure around our radiation sources, which reduces environmental and public exposures to negligible levels, I believe that the requirement for such programs should be made on an organisational/operational basis.</p> <p>Section 2.5 – Line 253 “clause 0”, should be “clause 2.4”.</p> <p>Section 3 – Line 261 “occupational exposure (section 3.1)”, should be “occupational exposure (section 3.2)”.</p> <p>Section 3.1.1 – Line 269 “Protection” and “Safety” are synonyms. See further comments for Glossary below.</p> <p>Section 3.1.3 Hierarchy of controls: List to include additional point on substitution after point a) elimination, for example “b) substitution of the radiation exposure hazard with something safer, e.g. less Bq, lower energy emissions, etc.”</p> <p>Section 3.1.3 – Line 283 Current point c) is an administrative control. Recommend moving to end of point d) (line 284 and 285): “(d) application of administrative controls through work procedures, training, installation of warning signs and labels, and restricting access to radiation by designation of controlled and supervised areas.”</p> <p>Section 3.1.8 – Line 314 “qualified expert”, what is ARPANSA’s opinion of who this could be? How will they be identified? GSR Part 3 2.21.(b) states that “The government shall ensure that requirements are established for: (b) The formal recognition¹² of qualified experts; ¹² ‘Formal recognition’ means documented acknowledgement by the relevant authority that a person has the qualifications and expertise required for the responsibilities that he or she will bear in the conduct of the authorized activity.”</p>	<p>equipment. If not then the requirement for authorisation is within the regulator’s control in the application of a graded approach.</p> <p>The relevant regulatory authority will determine the extent of this monitoring program consistent with a graded approach. This determination should be based on exposure history and modelled risks.</p> <p>This line states 2.4.</p> <p>Amended.</p> <p>‘protection and safety’ is specifically defined in the Glossary.</p> <p>Done.</p> <p>Done.</p> <p>This is defined in the Glossary. It is envisaged that a uniform approach to recognition of the ‘qualified expert’ would be adopted among the relevant regulatory authorities.</p>

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		<p>Section 3.1.11 – Lines 320 & 327 “person”, is this the Responsible Person? If not, will ARPANSA be issuing authorisations to all individuals that undertake such actions as specified in clause 3.1.10?</p> <p>Section 3.1.25 – Line 408 “radiation generators”, include in Glossary, see: GSR Part 3 page 422.</p> <p>Section 3.2.9 – Line 497 “activities relevant to protection and safety”, any examples?</p> <p>Line 498 “appropriate education, training and qualification”, will ARPANSA be providing guidance on what this could be for “activities relevant to protection and safety”?</p> <p>Line 514 “Special arrangements for protection and safety for female workers and for persons under 16 years of age”. What about persons under 18 years of age undergoing training? GSR Part 3: Requirement 28, 3.116. See further comments for Dose Limits below.</p> <p>Section 3.2.12 – Line 516 Should include provision for breastfed infants, as such: “The Responsible Person must ensure that when an occupationally exposed female has declared to the Responsible Person that she is pregnant,” or is breastfeeding, “additional controls are considered to protect the embryo/foetus” and breastfed infants “to a level similar to that provided for members of the public.”</p> <p>Section 3.2.13– Lines 519-521 Clause 3.2.13 is not as restrictive as GSR Part 3, 3.115, which states “Employers, registrants and licensees shall ensure that no person under the age of 16 years is or could be subject to occupational exposure.” Does ARPANSA intend to allow occupational exposures to persons under the age of 16 years, provided the public limits are not exceeded?</p> <p>Section 3.3.3(i) – Lines 577 “made available”, to whom? Any particular people or organisation? Any member of the public?</p> <p>Schedule A – Line 583</p>	<p>This is any person, natural, corporate or Responsible. Not all these dealings will be necessarily authorised by a given relevant regulatory authority but it is there to ensure that a person will check with their relevant regulatory authority if an authorisation is required.</p> <p>GSR Part 3 definition added to the Glossary</p> <p>Wording changed to reflect the requirement in clause 9.1 of the National Standard part of RPS1</p> <p>Sub-clauses (a) and (b) will ‘define’ this in accordance with a graded approach.</p> <p>A Radiation Health Committee decision was made that those over 16 will be treated as adults, acknowledging that requirements taken from GSR Part 3 needs to be in an Australian context. A dose constraint will be a valuable operational tool in this case.</p> <p>Done.</p> <p>Yes. If an employee under 16 is subject to any exposure no matter how low, then it is occupational exposure. The public limit is however an appropriate limit to this exposure.</p> <p>The ‘as appropriate’ here is a qualifier. There might be reasons that the public shouldn’t see the results (e.g. security implications) but otherwise, why shouldn’t they be able to see the assessments of doses from public exposure?</p>

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		<p>“Annual equivalent dose in: the lens of the eye” states “20 mSv” only. This is more restrictive than GSR Part 3, Schedule III.1.(b), which states “An equivalent dose to the lens of the eye of 20 mSv per year averaged over five consecutive years (100 mSv in 5 years) and of 50 mSv in any single year;” i.e. making it in the same as effective dose limitation. Does ARPANSA intend to make exposures to the lens of the eye more restrictive than those for effective doses? Recommend adoption of GSR Part 3 wording.</p> <p>Line 591</p> <p>Include additional sentence as per GSR Part 3, footer 67, p132, “The dose to the skin also contributes to the effective dose, this contribution being the average dose to the entire skin multiplied by the tissue weighting factor for the skin.”</p> <p>GSR Part 3, Schedule III.2. (a), (b), and (c) covers dose limits for “occupational exposure of apprentices of 16 to 18 years of age who are being trained for employment involving radiation and for exposure of students of age 16 to 18 who use sources in the course of their studies”. Does ARPANSA intend to apply the occupational or public dose limits for this group?</p> <p>Suggestion for ARPANSA consideration: Female workers of reproductive capacity - No more than 13 mSv equivalent dose to the abdomen per any three month period. (This additional restriction is to protect a recently conceived foetus within a female worker who may be unaware of her pregnancy).</p> <p>Ref: <i>UK HSE, Work with ionising radiation, Ionising Radiations Regulations 1999, Approved Code of Practice and guidance</i></p> <p><i>Women of reproductive capacity: Without prejudice to paragraphs 1 and 3 [note: these refer to effective dose limits], the limit on equivalent dose for the abdomen of a woman of reproductive capacity who is at work, being the equivalent dose from external radiation resulting from exposure to ionising radiation averaged throughout the abdomen, shall be 13 mSv in any consecutive period of three months.</i></p> <p>Schedule B – Line 601</p> <p>Include additional sentence as per GSR Part 3, footer 67, p132, “The dose to the skin also contributes to the effective dose, this contribution being the average dose to the entire skin multiplied by the tissue weighting factor for the skin.”</p> <p>Page 23 - Requirement 28</p> <p>Not fully covered by RPS C-1, see comments above.</p> <p>Glossary Lines 676, 697</p> <p>“Absorbed dose” not defined. Should be included, as in RPS1.</p> <p>“w_R, radiation weighting factors” and “w_T, tissue weighting factors” not included.</p>	<p>Done.</p> <p>Done.</p> <p>It is expected that a dose constraint consistent with the public dose limit would apply here but there might be circumstances where higher levels would be warranted.</p> <p>No, not at this time. It is expected that this will be discussed with the IAEA during preparation of the next version of GSR Part 3.</p> <p>Done.</p> <p>Noted. Changed to ‘16’.</p> <p>‘Absorbed dose’ added to the Glossary. ‘w_R’ and ‘w_T’ added to the Glossary.</p>

#	SUBMITTER	COMMENT	RESPONSE
6	SA EPA	<p>Were in RPS1 and should be here, as stated by ARPANSA in Statement on Proposed Changes to Australia’s Radiation Protection Standards (January 2010). See GSR Part 3, pages 411 and 425 for w_R and w_T, respectively.</p> <p>Line 702 Define “detriment”, for example: Detriment represents a balance between cancer incidence, cancer mortality, life shortening and hereditary effects.</p> <p>Lines 704-705 Can ARPANSA please provide guidance of what can help with these decisions? Such as GSR Part 3 p416-417, Relative Biological Effectiveness (RBE).</p> <p>Line 797 Replace “social” with “societal”, ICRP 103</p> <p>Line 817 Input a paragraph break after “...if they do occur.”, as in GSR Part 3, p408.</p> <p>Line 830 Will ARPANSA be publishing or referring to guidance documentation, like IAEA RS-G-1.4, to help Responsible Persons, and potential Qualified Experts attain this recognition?</p> <p>Line 836 Recommend including a paragraph break at end of first sentence, and then include a new header stating Ionising radiation.</p> <p>Define “radiation generator” as per GSR Part 3, p422.</p> <p>Line 850 Define “radioactive substance”, as per GSR Part 4, p412. Suggested wording “A radioactive substance exhibits radioactivity, but gives no indication of the magnitude of the hazard involved. In other words, all radioactive material may be considered radioactive substances, but not all radioactive substances may be considered radioactive materials.”</p> <p>Line 872 Include explanatory statement that this is a generalised usage of the term ‘safety’ (i.e. to mean protection and safety).</p> <p>I don’t have too many comments on this. I think it’s pretty good and most of it is covered by our current regulations. There is some duplication of some of the responsible person requirements across the general requirements and the requirements for Occupational exposure but not sure if this can be avoided? There</p>	<p>‘Detriment’ is only used in the Glossary.</p> <p>This information could be provided in guidance documents to come later.</p> <p>Done.</p> <p>Done.</p> <p>This information could be provided in guidance documents to come later.</p> <p>OK to the paragraph break. No to the new header. ‘Ionising radiation’ is not used in the document as the PEC only relates to ionising radiation anyway.</p> <p>Done.</p> <p>Clarified version of the GSR Part 3 version added.</p> <p>This is as taken from GSR Part 3.</p>

#	SUBMITTER	COMMENT	RESPONSE
7	Minerals Council of Australia	<p>are a couple of things I would like to mention;</p> <ul style="list-style-type: none"> The code talks about human imaging for detection of concealed objects etc but what about the use of bomb detection equipment (radiography) for bomb detection and as a result exposure of people to radiation? This came to light with the collar bomb issue in NSW a few years ago. Although this could be more suitable in the Emergency Exposure Code as they are likely to be one events? Loch Castle and myself were going to put a RHC paper together regarding this topic earlier this year as it has been an issue for some jurisdictions. We just never got around to it! There was a emergency services training course held in Tasmania earlier this year related to this. 3.1.20 "Dose Limits": I believe there should be a clause that refers the responsible person to undertake an appropriate review and notify the regulatory authority if a dose limit is exceeded. <p>The Minerals Council of Australia (MCA) welcomes the opportunity to provide comment to ARPANSA on the draft Code for Radiation Protection in Planned Exposure Situations (the Proposed Code).</p> <p>Relevance to Australia's uranium industry</p> <p>The MCA is the peak industry organisation representing Australia's exploration, mining and minerals processing industry, nationally and internationally in their contribution to sustainable development and society. MCA member companies represent more than 85 per cent of Australia's annual minerals industry production and a higher share of minerals exports.</p> <p>Uranium exploration, development and mining company members of the MCA meet regularly as the MCA Uranium Forum. Members of the MCA Uranium Forum are focused on safely and responsibly exploring for, developing and producing uranium exclusively for peaceful uses; that is for the production of low emissions electricity, nuclear research, nuclear medicine and industrial applications.</p> <p>Key recommendations</p> <p><i>1. Section 2.2: Optimisation and Limitation</i></p> <p>The MCA submits that Section 2.2: Optimisation and Limitation combines two very different concepts and that they should not be combined into one section.</p> <p>Recommendation: The MCA strongly recommends that this section be rewritten, in three separate sections; justification, optimisation and limitation. Appendix A includes suggested text for this purpose.</p> <p><i>2. Optimisation</i></p> <p>Optimisation is more complex than the Proposed Code focusing on dose constraints covers. The Proposed Code does not refer to ALARA and the MCA submits that this</p>	<p>Noted.</p> <p>Clause 3.1.20(f) addresses this matter since exceeding statutory dose limit constitutes an accident.</p> <p>Noted.</p> <p>Noted.</p> <p>This is acknowledged, however this section on objectives is to inform the purpose of mandatory requirement, rather than being requirements themselves. Optimisation and limitation both relate to the control objectives of the regulatory framework.</p> <p>The Code addresses optimisation under 2.4 graded approach, and section 3 contains details of what a Responsible Person must</p>

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		<p>is a flaw in the document as drafted.</p> <p>Recommendation: The MCA recommends that the section on optimisation describes ALARA and the ALARA process, and provides some guidance and direction on the ALARA process as reflected in Appendix A.</p> <p><i>3. Graded Approach to Regulation</i></p> <p>The MCA supports and commends ARPANSA on outlining a graded approach to regulation. This concept is mentioned many times in the Proposed Code. However, there is no guidance for its application apart from broad statements in Section 2.4. Since the scope of the Proposed Code is so broad, there may be many new operators and regulators who will be required to comply.</p> <p>Recommendation: The MCA recommends that clearer advice be provided to regulators on the concept of a 'graded approach to regulation' and its practical implementation.</p> <p><i>4. Scope of Application of the Proposed Code</i></p> <p>The MCA submits that the scope of application of the Proposed Code requires further clarification.</p> <p>In Section 1.4 of the Proposed Code, the scope is outlined. It is noted that the scope is very large, from 'activities within the nuclear fuel cycle' to 'use of material for education'. In practice, the MCA notes that it is difficult to apply one simple set of rules to such a broad range of radiation situations and simple statements leave too much to interpretation.</p> <p>The MCA submits that more guidance on the graded approach to regulation will be useful in clarifying the issues associated with such a large scope.</p> <p>Recommendation: The MCA recommends ARPANSA provide more guidance and clarity on when and where specific aspects of the Proposed Code apply. For example, it would be useful to provide a matrix which includes; radionuclide concentrations, volumes, processes, activities and the level of protection required.</p> <p><i>5. Dose Constraint</i></p> <p>The MCA submits that there are mixed messages throughout the Proposed Code on dose constraint. It is initially noted as a tool for optimisation by the operator (Section 2.2.1) and then later in the Proposed Code, the implication is that it must</p>	<p>do in order to satisfy authorisation requirements of the relevant regulatory authority. It is also addressed in the <i>F-1 Fundamentals</i>. However, the RHC agrees that optimisation is complex, and it is a vital aspect of the radiation safety framework. Its practice necessarily varies between sectors. ARPANSA and the RHC would be keen to work with the MCA to discuss how optimisation can be most effectively applied in the minerals sector, and how guidance can assist this application.</p> <p>Guidance documents on how to apply the graded approach to different industries (e.g a dental practice, a hospital, an irradiation facility, a mining operation, a reactor) are intended to be published following the promulgation of the PEC. There is no intention to use this Code to widen the range operations that come under the system of regulation. As noted, the RHC would be keen to work with the MCA to determine what advice might most effectively clarify the application of a graded approach.</p> <p>Agreed, and as noted above, guidance documents are intended to be published later.</p> <p>While acknowledging that further guidance will continue to improve radiation regulation in Australia, many of the requirements in the draft Code were requirements in RPS1.</p> <p>Correct.</p> <p>The dose limits are those that will be applied by regulators, not the dose constraints. Misapplication of a dose constraint as a</p>

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		<p>be mandatorily applied (Section 3.1.13).</p> <p>The MCA is also concerned that despite the good intention of a dose constraint, there is a real risk that in practice, it will become a new limit.</p> <p>Recommendation: The MCA recommends that clear guidance be provided on dose constraints. It is proposed that the operator is in the best position to set dose constraints. It is also recommended that a clear statement be made that a dose constraint is not a de facto limit.</p> <p>6. Risk Constraint</p> <p>The MCA submits that Section 2.2.2: Risk Constraints is a new concept and includes a level of complexity that is not generally necessary.</p> <p>Recommendation: The MCA recommends that clear guidance on when and where this concept might be applied must be provided.</p> <p>Further MCA comments and recommendations on specific sections</p> <p>Line 58</p> <p>The MCA seeks clarification whether the Proposed Code supersedes the Code of Practice and Safety Guide for Radiation Protection and Radioactive Waste Management in Mining and Mineral Processing ('Mining Code').</p> <p>Line 154</p> <p>It is important to note that 'Optimisation and Limitation' are not the same concept and need to be separated. The focus of this section is constraints and the implication is that a dose constraint is the main way to optimise. This is fundamentally incorrect. There is no discussion on limits in this section, again suggesting that the dose constraint is a de facto limit.</p> <p>Line 177</p> <p>Risk Constraint is a new concept. Guidance on its application is required, otherwise there is a risk of making situations more complex than they need be.</p> <p>Lines 197-198</p> <p>Suggest 'reduce' rather than 'restrict'.</p> <p>Lines 249-250</p> <p>This sentence does not fit under section 2.5 – suggest moving to section 3.1.</p> <p>Lines 253-256</p> <p>This is obvious and highlights the problem with such a wide scope. It is suggested that guidance is provided rather than noting that the controls will be less for smaller sized sources.</p> <p>Line 263</p>	<p>'limit' (which is known to be occurring overseas for air crews for example), can have detrimental outcomes, and there is a role for the regulator and peak bodies in the development of guidance and education of the Responsible Person.</p> <p>It is felt that risk constraint is adequately covered in clause 2.2.2, remembering that this is only for information purpose and not used in the mandatory requirements. As a component of IAEA GSR Part 3, risk constraints are an internationally accepted concept. Risk constraints are likely to be less relevant in a sector such as the minerals industry, which deals more with low specific activity sources.</p> <p>It does not. However, there is an opportunity for interested parties to work towards better standards, codes and guidance.</p> <p>Discussed above. This section is for information purposes.</p> <p>Discussed above. This section is for information purposes.</p> <p>Noted, however this is quoting the <i>Fundamentals</i> and that is the word used.</p> <p>Agreed but moved to be the last paragraph of the introductory section of Chapter 2 (just before 2.1 Justification).</p> <p>Noted. As discussed, guidance documents are intended to follow the publishing of the Code.</p>

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		<p>Replace 'degree' with 'degrees'.</p> <p>Lines 265/271</p> <p>There is swapping between 'risk' and 'hazard' – these terms have different meanings. It is suggested that the use of these words need to be precise.</p> <p>Lines 302-308</p> <p>Suggest deleting or broadening to say that 'the operator will be subject to a range of requirements as part of their legal obligations under various health and safety Acts and regulations'. This sits better in the section starting at line 317.</p> <p>Line 326</p> <p>'Source' does not seem to be defined in the document.</p> <p>Line 364</p> <p>There is a need to be specific about 'safety assessments'. The term has a specific meaning in other jurisdictions (such as occupational health and safety (OHS) regulations).</p> <p>Line 446</p> <p>Suggest that the title should read 'Responsibilities of the Responsible Person for the MONITORING of Workers'. Suggest also that this paragraph could be moved to the beginning of the later section on Monitoring and Reporting (line 539).</p> <p>Line 454</p> <p>Suggest new line as follows; 'e) Appropriate monitoring methods'.</p> <p>Lines 455-458</p> <p>Suggest that Section 3.2.2 does not belong in this section – it is about dose limits and the previous paragraph is about monitoring.</p> <p>Line 476</p> <p>The footnote in this line (footnote 4) refers to a 'site radiation management committee'. This should be deleted or changed to a 'site health and safety committee' to fit in with existing OHS requirements (and avoid the implication for the addition of a new committee).</p> <p>Lines 515-518</p> <p>Section 3.2.12 - This needs to be linked to the worker requirement at 3.2.3(g).</p> <p>Line 568</p> <p>Add another line to note that a 'capability to monitor is maintained in normal operating conditions'.</p>	<p>Done.</p> <p>Agreed, 'risks' changed to 'hazard' in 3.1.2</p> <p>Could be deleted however, it provides reference information to a 'newcomer' to the industry. Jurisdictional legislation will be the final word here.</p> <p>Changed to 'radiation source', which is defined.</p> <p>3.1.17 to 3.1.19 informs 'safety assessments' in more detail.</p> <p>This pair of requirements relates to both monitoring and protection. The title is therefore OK. Given that they are referring to occupational exposure, the location is appropriate.</p> <p>Agreed.</p> <p>Disagreed, these tie in well enough to stay together under the broader heading of 'protection of workers'.</p> <p>It is an example only. If the existing site health and safety committee can meet this function, then that is acceptable. Some Responsible Persons might have a dedicated radiation management committee.</p> <p>Both clauses stand on their own.</p> <p>No, not all users will require monitoring in normal operating conditions (e.g. a dentist) however, they would in an emergency situation.</p>

#	SUBMITTER	COMMENT	RESPONSE
		<p>Line 580 Suggest that the Proposed Code should end with a short summary.</p> <p>APPENDIX A Alternate Section 2.2 of the Proposed Code 2.2 Limitation In planned exposure situations, dose limits shall apply which represents the upper bounds of dose which is acceptable. The dose limits are based on international guidance and recommendations and are defined in Appendix XX. The dose limits are dependent on the nature of the exposure and includes special case exposures. The broad groups are normal workers over extended periods, special case doses for shorter exposures (1 year), special case workers (under the age of 18), protection of the foetus in pregnant workers and protection of members of the public. The dose limits form the boundary for what would be legally acceptable and as such should not be exceeded in any planned exposure. The limits have been set at a level which is deemed to represent an acceptable level of industry and public risks and as such do not form a definition between safe and unsafe. Exposures over the limit may be subject to legal action but may not represent a significant increase in the risk for the person exceeding the limit.</p> <p>2.3 Optimisation Optimisation is the process by which doses below the dose limits are controlled and kept at a level reflecting good practices and appropriate radiation practices. There are three main principle mechanisms utilised within optimisation, the As Low As Reasonably Achievable (ALARA) principle, Dose Constraints and Risk Constraints.</p> <p>2.3.1 ALARA ALARA (As Low As Reasonably Achievable, societal and economic factors being taken into account) is the principal mechanism by which doses have been reduced in practical radiation protection situations. The key to the ALARA principle is the use of the term reasonable and how its use takes into account societal and economic factors. Doses should be minimised to the extent which is possible within reasonable bounds but not to an extent which give rise to costs (either to society or the economics of the operation) which are which are not commensurate to the dose reduction. This is important since as the dose is reduced, there are points of diminishing returns beyond which any further reduction is unlikely to be practical or justifiable.</p> <p>2.3.2. Dose Constraints In planned exposure situations, a dose constraint provides a prospective source–</p>	<p>Noted.</p> <p>Noted. See above discussion.</p>

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		<p>related value of individual dose, which is set below the dose limit. It is a tool to be established and used in the optimisation of protection and safety by the person or organisation responsible for a source, facility or an activity. Dose constraints are not dose limits but will support actions to prevent dose limits to be exceeded; however, exceeding a dose constraint does not represent non-compliance with regulatory requirements but could result in follow-up actions.</p> <p>For occupational exposure the dose constraint is a value of individual dose used to narrow the range of options for managing the exposure such that only options resulting in a dose below the constraint are considered in the planning process. Actual doses are, thus, normally expected to be below the dose constraint.</p> <p>For public exposure in planned exposure situations, the regulatory body ensures the establishment or approval of dose constraints, taking into account the characteristics of the site and of the source, facility or activity, the scenarios for exposure and the views of interested parties. Measures should then be undertaken to optimise protection at or below the dose constraint and, as for occupational exposure, actual exposures are normally expected to be below the constraint.</p> <p>After exposures have occurred, the dose constraint may be used as a benchmark for assessing the suitability of the optimised strategy for protection and safety (referred to as the protection strategy) that has been implemented and for making adjustments as necessary. The setting of the dose constraint needs to be considered in conjunction with other health and safety provisions and the technology available.</p> <p>2.3.3 Risk Constraints</p> <p>Exposures may be either certain or almost certain to occur, or potential which means that they are not expected to occur but may do so under certain circumstances. Such potential exposures may be more appropriately approached by constraining the risk, or setting a risk target that e.g. outlines the requirements for protective capability of a disposal facility for radioactive waste in the distant future. The risk constraint or target can be formulated as the product of probability of the exposure, and resulting consequence. Optimisation can also be applied to reduce the risk. Dose constraints and risk constraints or targets can be used in combination. The ambition is to reduce all doses to levels that are as low as reasonably achievable, economic and societal factors being taken into account.</p>	