Summary of submissions and responses

Title of document: Radiation Protection in Medical Exposure

Period of comment: 23 Feb 2018 – 25 May 2018

| # | Commenter | Line | Clause | Comment | Response |
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| 295 | WA Radiological Council | 94 | Foreword | The foreword states that the MEC sets out “regulatory requirements”. The word “regulatory” needs to be removed as the MEC is not legislative, this would also make it consistent with the PEC. | Agree |
| 1 | Geraldine Robertson | 108 | Foreword | So many codes leads to confusion. Could you add a table listing the codes (4?) and their purpose? Isn’t there a code covering the WORKFORCE- see line 200­ | A table is not appropriate for the foreword. Added Appendix 2 listing related Codes and Guidance. Expanded footnote 1 [under 1.4 Scope] to note that: "Appendix 2 lists related documents that address the areas not covered by this code and also lists relevant guidance related to this code." Occupational exposure is covered by the Planned Exposure Code (RPS C-1) |
| 62 | Peter Williams / Len Potapof | 108 | Foreword & 3.3.5 | RPS 4 The inclusion within this new draft Code of requirements for the release of patients after radionuclide therapy are supported. However, as RPS4 Recommendations for the Discharge of Patients Undergoing Treatment with Radioactive Substances (2002) contains a lot of practical information on methods to ensure compliance with the dose constraints specified in this part of the Medical Code it should be maintained until information is included in the subsequent new safety guide. | Keep RPS 4 until new safety guide incorporates guidance information. The IAEA safety guide (SSG-46) doesn't include the tables contained in RPS4 but instead references IAEA SRS 63, ICRP 94 and EC Rad Prot 97, all on release of patients. |
| 98 | Stewart Midgley | 109 | Safety Guides | Omission at Lines 109-112. Identify the documents involved are RPS 14.1, 14.2 and 14.3, and add these to the references. | Added specific mention of RPS 14.1, 14.2 and 14.3 Added Safety Guides to the list of references |
| 410 | QLD DoH | 111 | Foreword | “Until that time…..implementation of this publication”, will be redundant once this code is published hence there is no point of having it in this document. | Changed beginning of the sentence to "In the interim …". The guidance in the existing Safety Guides is still relevant and they can continue to be used in conjunction with the revised Medical Exposure Code while the process of reviewing and updating them is proceeding. |
| 21 | Penny Hill - ACT | 152 | 1.1 | Compare this citation with that used on line 176/177, which is longer (and better) than the citation shown at the start of the RPS C-1 document itself. No mention of radiation protection in the citation. | Keeping citation style for Medical Exposure Code consistent with the Planned Exposure Code Intended to allow the shortened form of citation |
| 22 | Penny Hill - ACT | 167 | 1.2 | limits -> prescribed limits | Agree |
| 23 | Penny Hill - ACT | 170 | 1.2 | add colon | Agree |
| 24 | Penny Hill - ACT | 178 | 1.2 | italicise title of RPS 14 | Agree |
| 25 | Penny Hill - ACT | 180 | 1.2 | move ‘medical exposure’ | Agree |
| 26 | Penny Hill - ACT | 186 | 1.3 | Which/that | The writing style of the document is consistent with that in the Planned Exposure Code (RPS C-1) |
| 262 | Victorian Department of Health and Human Services | 192 | 1.4 | Scope Clarification: Willing volunteers i.e. parents (not nursing staff) is meant when referring to volunteer. Does not cover dental and chiropractic practices as their respective Codes will be maintained. Reason being that it was more practical from a time perspective. | Noted. (Documentation of clarifying remarks in relation to the stated scope as made at a public forum) |
| 298 | WA Radiological Council | 192 | 1.4 Footnote 2 | Previous comment: WA does not have “dose constraints” for medical exposures Current comment: WA does not have “dose constraints” for medical exposures. | Noted. Footnote is indicating tools that are available to ensure that patient doses are commensurate with the clinical purpose. |
| 257 | Victorian Department of Health and Human Services | 196 | 1.4 | The sentence “The requirements of this Code should be applied using a graded approach and interpreted accordingly” should be removed as it gives the impression that the licensee can decide what constitutes minimum level of compliance. This sentence is applicable to the Regulatory Authority more than the Licensee. | This phrase is being inserted into codes such as this at the insistence of a couple of jurisdictions, one of which was Victoria. |
| 258 | Victorian Department of Health and Human Services | 198 | 1.4 | The sentence “Not all requirements specified in this Code are relevant for every medical radiation facility” raises the question which requirements are relevant. Headings and clauses in the Code should be written in a way that is clear to the reader as to whether or not a requirement applies to a particular practice, in which case this sentence is not necessary. | Disagree. This code relies in large measure on a well-educated medical radiation workforce. If a regulator is incapable of discerning when certain requirements become relevant, it would be prudent for that regulator to determine what representative from the relevant professions think is reasonable. However, the plight of the regulator and the regulated will be assisted by the production of guidance materials which will clarify which requirements apply in a circumstance. |
| 198 | Diagnostic Imaging Accreditation Scheme | 199 | 1.4 | Usability It would be helpful to define which ARPANSA Codes address the matters referred to in this section, which the draft Code does not address. | Added Appendix 2 listing related Codes and Guidance. Expanded footnote 1 to note that: "Appendix 2 lists related documents that address the areas not covered by this code and also lists relevant guidance related to this code." |
| 2 | Geraldine Robertson | 200 | 1.4 (a) | Which code covers this? | Planned exposure code (RPS C-1) |
| 3 | Geraldine Robertson | 209 | 1.4 | I don’t understand what this means | Dose limitation does not apply to medical exposures. Doses should be commensurate with the clinical purpose and the benefit should outweigh the risk. |
| 340 | ACPSEM | 221 | 2.1 | Introduction To truly achieve the objectives outlined in this introduction, the application of radiation to achieve a diagnostic or therapeutic outcome must be considered as an integral part of an overall clinical governance process. The audit and reporting of radiation use along with its diagnostic and therapeutic outcomes must therefore form part of any clinical program’s governance processes either at an institutional or profession level. | Noted |
| 27 | Penny Hill - ACT | 222 | 2.1 | Protection during, radiation protection | Agree |
| 28 | Penny Hill - ACT | 226 | 2.1 | reverse images and information, which/that | Disagree |
| 29 | Penny Hill - ACT | 230 | 2.2 | Principles of/for Consistency with the title? Or the body of the paragraph? | Principles for |
| 341 | ACPSEM | 245 | 2.2.1 | Justification Implementation process and evidence required for compliance needs to be defined. More details are required to understand the impact this might have on the patient workflow and health systems. | Section 2 outlines the basic principles of protection. Detailed requirements are contained in Section 3 |
| 299 | WA Radiological Council | 247 | 2.2.2 | Optimisation Pre-existing but RPS14 referred to ALARA specifically – this is preferable. DRLs – amend last sentence to “review and justify procedures” | changed text to "review procedures and revise or justify as appropriate" |
| 342 | ACPSEM | 250 | 2.2.2 | Optimisation Clarification on what constitutes special attention is needed. GSR3 is distinct about optimisation requirements and the essential role of the Medical Physicist as part of a multi-disciplinary team. There are specific clinical exposures techniques spearheaded by diagnostic medical physicist e.g. clinical DRLs and weight based protocols for paediatric CT. Requirement fails to recognise International Best Practice in these relatively higher risk groups and the significant importance of the medical physicist; highly skilled in patient dosimetry and a valuable resource in image optimisation and patient protection. NB. Evidencing requirements {3.5.3 (b)} imposed by the relevant regulatory authorities must not impede the clinical expertise and recommendation of the experts (RANZCR, ACPSEM, ASMIRT); to ensure optimal clinical care for medical exposures | Section 2 outlines the basic principles of protection. Detailed requirements are contained in Section 3 |
| 30 | Penny Hill - ACT | 253 | 2.2.2 | Capitalise ‘Diagnostic reference levels’ | Agree |
| 263 | Victorian Department of Health and Human Services | 258 | 3.1 | Responsibilities specific to medical exposure Responsible Person - Clarified that this, in the Victorian context, is the management licence holder | Noted. (Documentation of clarifying remarks as made at a public forum) |
| 147 | Australian Society of Medical Imaging and Radiation Therapy (ASMIRT) | 260 | 3.1.1 | Section 3.1.1 This section attempts to cover both diagnostic and therapeutic procedures and in doing so is unclear. | The working group considered a separate stream but after some discussion came to the conclusion that the existing text was adequate, provided the “communication” process was understood in a broad context as discussion within the care team as to appropriate imaging or treatment. |
| 148 | Australian Society of Medical Imaging and Radiation Therapy (ASMIRT) | 261 | 3.1.1 (a) | Line 261 (a) For radiation therapy, the procedure is not requested by the referrer. The referrer makes a referral to the radiation oncologist, who then determines the appropriate treatment. In this context the Responsible Person is firstly the oncologist who determines the need for radiation therapy and secondly the two radiation therapists who deliver the radiation therapy on a daily basis. | The Responsible person is the CEO of the treatment facility who has ultimate responsibility for policies and procedures. The oncologist is the radiological medical practitioner, the therapists are the “operator” in the Code. |
| 264 | Victorian Department of Health and Human Services | 261 | 3.1.1 (a) | Control of medical exposures 3.1.1a Comment: The term "clinical context" not seen before, this is usually referred to as "clinical question". It was also noted that this is the only time it appears. | The information required is more than simply the clinical question being asked. It also includes details such as symptoms and associated matters such as pregnancy. Changed 'clinical context' to 'clinical indication' |
| 384 | ADIA | 261 | 3.1.1 (a) & (b) | The Code should make clear that self-referral by a radiologist is acceptable, as the definition of “Referrer” in the glossary could be interpreted as requiring all examinations to be referred by a third-party. There are many instances where self-referral by a radiological medical practitioner is appropriate. | It is possible for the referrer and the radiological medical practitioner to be the same person. Clinical indications and patient identification should be recorded as per 3.1.10. The same would apply to substitution of a more appropriate procedure or authorisation of additional procedures stemming from initial findings. See 3.1.10 where RMP is also referrer. |
| 342 a | ACPSEM | 262 | 3.1.1 (a) | “Clinical context” is a newly used phrase and could be interpreted many ways without further guidance/definition. | Changed 'clinical context' to 'clinical indication' |
| 99 | Stewart Midgley | 263 | 3.1.1 (b) | 3.1.1 (b). “Communication” implies a two way dialog. The referral process would usually be a written request, then selection of the appropriate modality and scan protocol by the radiological medical practitioner. Workload restricts two way dialog to a very small fraction of incoming requests. Perhaps the intention here is to request documentary evidence (hard or soft copy) that the written referral exists and includes information that would facilitate any necessary dialog between the referrer (name and contact details) and radiological medical practitioner. | A footnote has be added to indicate that: "A written request with adequate clinical information on which to base a justification will usually meet the requirement for communication. However, contact information for the referrer must be provided to facilitate further communication, should it be required." |
| 132 | Glenn Gillett | 263 | 3.1.1 (b) | 3.1.1 (b) justification, communication between - Perhaps this clause could be reworded to something like “the medical exposure has been justified by the radiological medical practitioner and as appropriate after communication with the referrer, or it is part of an approved health screening program”. The aim of the rewording is to make communication between the RMP and referrer more on an as required basis, rather than more of a mandatory basis. | Communication includes the information on the referral. If the referral provides sufficient detail the radiological medical practitioner can perform the justification without any further communication with the referrer. Change to: “the medical exposure has been justified by the radiological medical practitioner following communication with the referrer, as appropriate, or it is part of an approved health screening program” |
| 149 | Australian Society of Medical Imaging and Radiation Therapy (ASMIRT) | 263 | 3.1.1 (b) | Line 263 (b) it is unclear what is meant by this. What is the context of “as appropriate” and in what circumstances would this be required for radiation therapy? If it is meant to ensure that potentially inappropriate requests for either medical imaging or radiation therapy do not progress, but rather are further discussed between the radiologist/radiation oncologist and the requester, then that is good. | Communication between healthcare professionals occurs as required to ensure that appropriate imaging or treatment is selected |
| 150 | Australian Society of Medical Imaging and Radiation Therapy (ASMIRT) | 263 | 3.1.1 (b) | Line 263: b) assume communication is via referral for procedure? There is rarely communication beyond that. | Yes, and if the referral provides the necessary information to justify the medical exposure no further communication may be required. However, if more information is required there must be further communication. |
| 201 | Diagnostic Imaging Accreditation Scheme | 263 | 3.1.1 | Requesting  This point leads the reader to believe that each examination requires a third party request. There are many situations where self-referral by the radiological medical practitioner is appropriate. | It is possible for the referrer and the radiological medical practitioner to be the same person. Clinical indications and patient identification should be recorded as per 3.1.10. The same would apply to substitution of a more appropriate procedure or authorisation of additional procedures stemming from initial findings. See 3.1.10 where RMP is also referrer. |
| 248 | Anonymous | 263 | 3.1.1 (b) | 3.1.1(b) needs modification to "justified by...the referrer" Dental specialists and dentists also refer for 2D & 3D radiology. | Definition of Referrer includes dentists and dental specialists referring (or self-referring) for imaging Change to: “the medical exposure has been justified by the radiological medical practitioner following communication with the referrer, as appropriate, or it is part of an approved health screening program” |
| 265 | Victorian Department of Health and Human Services | 263 | 3.1.1 (b) | 3.1.1b Comment: Clarify the justification by means of communication. A view that this would be too onerous. Comment: This arrangement would be impossible. E.g. with the example of a tele radiologist, this would not work. The emphasis is different. If there are issues only then would you refer back to the referrer. | Provided referral contains sufficient information, this would constitute the necessary communication. If the referral doesn’t contain sufficient information, then further communication may be necessary. Change to: “the medical exposure has been justified by the radiological medical practitioner following communication with the referrer, as appropriate, or it is part of an approved health screening program” |
| 343 | ACPSEM | 263 | 3.1.1 (b) | More information is needed on: How do the relevant regulatory authorities view justification communication, what is appropriate and how is this to be evidenced for compliance | Normally the relevant information would be documented in a referral, and where that is insufficient further communication should take place. Records of referral would be kept as evidence. |
| 385 | ADIA | 263 | 3.1.1 (b) | The Code should make clear that communication “as appropriate” between the radiological medical practitioner and the referrer can be satisfied in most cases by the request form. Additional communication beyond the request form in all cases would add considerably to the workload of radiologists and referrers. | A footnote has be added to indicate that: "A written request with adequate clinical information on which to base a justification will usually meet the requirement for communication. However, contact information for the referrer must be provided to facilitate further communication, should it be required." |
| 411 | QLD DoH | 263 | 3.1.1 (b) | “the medical exposure has been justified by means of communication between the radiological medical practitioner and the referrer”; this statement is quite broad and isn’t practical. The radiologist isn’t on-site continuously and cannot provide justification for every medical exposure, before it commences. This statement should be more focussed to ensure communication between the radiological medical practitioner and referrer can occur when requested imaging is substituted for a more appropriate modality with a higher specific yield for the clinical question raised. | Dealt with by practice protocols for justification. Referral should normally contain sufficient information for communication. |
| 188 | Diagnostic Imaging Accreditation Scheme | 268 | 3.1.1 | Benefits and risks of radiological procedures Standard 2.2, Consumer Consent and Information Standard requires that patients have access to information about the diagnostic imaging procedure and that risks are advised to the patient or substitute decision maker prior to the service. The requirements in the draft Code are broadly consistent with the requirements in Standard 2.2. | Noted |
| 199 | Diagnostic Imaging Accreditation Scheme | 268 | 3.1.1 & 3.1.3 | Consent Consider strengthening the consent requirements by requiring that consent is obtained and recorded prior to a diagnostic imaging procedure being performed. | Noted |
| 266 | Victorian Department of Health and Human Services | 268 | 3.1.1 (d) | 3.1.1d Comment: This requirement adds a significant burden. Would the regulator or ARPANSA have a role in providing generic risk information in a central depository rather than everyone developing their own? | There is already significant knowledge and experience in this field. This requirement will prompt the various professions to produce generic risk information and guidance. ARPANSA need not necessarily be the place where such information is obtained. |
| 344 | ACPSEM | 269 | 3.1.1 (d) | Clarification on this statement is required: Does this mean that in diagnostic procedures the benefits and risks do not have to be explained? | Deleted parenthetical statement about diagnostic procedures, but added an initial statement 'whenever clinically practicable,…' |
| 4 | Geraldine Robertson | 271 | 3.1.1 (d) | (proposed addition) The patient or responsible person agrees to the procedure and this agreement is recorded/documented. Where the risk is high the patient must give written approval. | Added "3.1.1 (e) whenever clinically practicable, the patient or the patient’s legal authorised representative consents to the procedure." This is consistent with the DIAS Consumer Consent and Information Standard (DIAS Standard 2.2) |
| 31 | Penny Hill - ACT | 273 | 3.1.2 | Initial capitals? See https://www.nhmrc.gov.au/health-ethics/human-research-ethics-committees-hrecs | Agree |
| 268 | Victorian Department of Health and Human Services | 278 | 3.1.3 | 3.1.3 Comment: Some participants felt it is reasonable to release the patient with instructions but that they would not have the opportunity to advise the family members. Need to clarify expectations in final version. | The requirements are adequately detailed in 3.1.3. Nevertheless, guidance on their implementation would be helpful in some circumstances. Such guidance would be written in a safety guide or advice statements from one or more of the key professions. |
| 300 | WA Radiological Council | 278 | 3.1.3 | Disagree with definition of ‘medical exposure’ to include comforters and carers. Inclusion of diagnostic nuclear medicine - Patients should be discharged with written information and instructions. Not practicable for carers and comforters e.g. home-visiting nurse to “indicate an understanding”. | GSR Part 3 includes exposure of comforters and carers within medical exposure. Instructions not necessary following a diagnostic procedure Home-visiting nurse is not a “comforter or carer” under the definition (GSR Part 3 and Planned Exposure Code) and is receiving an occupational exposure. |
| 412 | QLD DoH | 278 | 3.1.3 | This clause refers to “….relevant information on radiation protection and information on…..”; clarification is required on what would be considered to be relevant information (e.g. a poster of equivalent doses for radiology). | Information available. This can be addressed in the Safety Guide. |
| 5 | Geraldine Robertson | 282 | 3.1.3 | (proposed addition) and consent is given and documented A repetition of addition to 3.1.1d but this reinforces the need to obtain and record consent | Agreed Note that in many cases involvement may be deliberately sought (eg a parent wanting to be with a child). |
| 151 | Australian Society of Medical Imaging and Radiation Therapy (ASMIRT) | 285 | 3.1.4 | Line 285-291: ASMIRT commends the recognition of a collaborative approach | Noted |
| 323 | RANZCR | 285 | 3.1.4 (a) & (b) | Suggest the wording be changed as follows to clearly state that regardless of who is performing the procedure e.g. a radiographer performing a chest radiograph or radiologist performing angiography, that the responsibility for radiation protection lies with the medical practitioner, unless the intent of this wording is to indicate someone else, but if so, who is this as you have suggested they are collaborating with the MIT and physicist, so the Responsible Person must be the radiologist. Clarification that the Responsible Person is in fact the radiologist in this situation is recommended, for example: 3.1.4 The Responsible Radiologist must ensure that: | The Responsible Person is the management license holder of the facility, who has overall responsibility for ensuring that there are policies and procedures in place that guide and direct the various professionals. The radiologist has the role of the radiological medical practitioner, and is responsible for the safety of the patient (3.1.1 (c) and 3.1.4 (a)), in conjunction with other professionals, as appropriate |
| 69 | Tomas Kron | 292 | 3.1.4 (b) | 3.1.4 (b) is training sufficient? Maybe certification? Documented competence? | Added a footnote after '…adequately trained in the appropriate area' to indicate that this is 'as acknowledged and assessed by relevant professional and regulatory bodies'. |
| 100 | Stewart Midgley | 292 | 3.1.4 (b) | 3.1.4 (b) These matters are better covered at 3.5.2. Query duplication | 3.1.4 (b) outlines the general requirement that personnel be trained. 3.5.2 addresses specific requirements in relation to training and certification. |
| 101 | Stewart Midgley | 292 | 3.1.4 (b) | “Adequately trained” might be defined in the glossary with examples such as registration by national organisations (RANZCR, AIR, ANZSNM, ACPSEM and others) accreditation or certification by these or other national bodies. The matter is reviewed by the local regulators as part of the licencing processes to use and also do something useful with ionising radiations. | Noted Added a footnote after '…adequately trained in the appropriate area' to indicate that this is 'as acknowledged and assessed by relevant professional and regulatory bodies'. |
| 269 | Victorian Department of Health and Human Services | 292 | 3.1.4 (b) | 3.1.4 (b) When is training deemed sufficient? Whether deemed competent is enough? In the situation where an orthopaedic surgeon is the clinician, thus would be the Radiation Medical Practitioner. Would that person have sufficient training in radiation protection? | This is a matter for the professions, AHPRA and the regulators. It would depend on the particular context. Again, helpful advice in a safety guide or in a paper written by one of the professions might provide sufficient information. |
| 301 | WA Radiological Council | 292 | 3.1.4 (b) | Amend to include “and authorised by the relevant regulatory authority” | Addressed by 3.5.2 (b) & (d) |
| 70 | Tomas Kron | 295 | 3.1.4 (c) | 3.1.4 (c) I believe that the activities described here must be fulfilled by a Medical Physicist – supervision (close? loose?) cannot be enough | Existing text of 3.1.4 (c) matches current requirements in RPS 14: 3.1.24 (b) and is in line with GSR Part 3 |
| 102 | Stewart Midgley | 295 | 3.1.4 (c) & (d) | 3.1.4(c,d) Certain organisations only employ trainees until qualified where upon they are deemed too expensive to retain and are replaced by another trainee. The following adjustment would assist in the eradication of this practice. Replace “under the supervision of a medical physicist” with “under the supervision of a qualified medical physicist” (or certified/accredited etc) | Noted. However the Code is deliberately allowing regulators to recognise persons other than Qualified Medical Physicists (per ACPSEM) as able to perform the functions of the medical physicist (see definition of medical physicist in the Glossary) |
| 152 | Australian Society of Medical Imaging and Radiation Therapy (ASMIRT) | 295 | 3.1.4 (c) | Lines 295-298: It is not clear how supervision in “under the supervision of a medical physicist” is defined. With respect to radiation therapy, some tasks such as dosimetry and quality assurance are undertaken independently (i.e. with no involvement of a medical physicist) for some patients/procedures whereas others would (such as patient specific QA for IMRT/VMAT). This varies from department to department. Perhaps better wording would be “in consultation with”. This clause also applies to the section on the website re “How has the draft code been changed?” The ability of radiation therapists to complete these tasks in consultation with medical physicists may allow for more flexibility and efficiency. | Added definition of dosimetry Dosimetry - the measurement, calculation and assessment of ionising radiation doses absorbed by organs and tissues within the human body |
| 270 | Victorian Department of Health and Human Services | 295 | 3.1.4 (c) & (d) | 3.1.4c/d Clarification: Both C and D are about having Medical Physicist involvement. Where in D you can have a more distant relationship. Comment: With vendors and application specialists doing a lot of the work at the moment, will this arrangement still be allowed? Comment: The statement about the Medical Physicist in the readers guide, why isn't this definition adopted in the Code's glossary? Comment: People advertising themselves as qualified Medical Physicists when not accredited. Is this an opportunity to close this gap in this Code? | The definition of ‘medical physicist’ is more generic than the commenter appears to have understood. The code specifies the level of involvement of medical physicists. The involvement could be through the development of routine tests with pass/fail parameters which are able to be properly tested by lesser qualified technicians. |
| 153 | Australian Society of Medical Imaging and Radiation Therapy (ASMIRT) | 299 | 3.1.4 (d) | Line 299-305: I think the issue here would be how supervision in “under the supervision of a medical physicist” is defined. | The "supervision" mentioned in the Code relates to advice and guidance and is not intended to mean direct, in-person supervision of the sort that would apply between a practitioner and a trainee. The relevant specialist expertise of the medical physicist in assessing and measuring patient dose, testing and performance of equipment, and calibration must be available to the other professionals at any given facility. This may be in the form of documented advice and protocols and need not necessarily be delivered in person by an on-site medical physicist. The level of involvement of medical physicists should be commensurate with the complexity and risk of the procedures undertaken at the facility. |
| 249 | Anonymous | 299 | 3.1.4 (d) & (e) | 3.1.4(d) & (e) has cost implications. | Agreed, but the costs will be minimal if a graded approach is applied. |
| 189 | Diagnostic Imaging Accreditation Scheme | 308 | 3.1.5 | Patient identification Standard 2.3, Patient Identification and Procedure Matching Standard requires that all patients must be correctly identified and matched to their intended procedure or treatment using a minimum of three patient identifiers. The identification requirements in the draft Code are broadly consistent with the requirements in Standard 2.3. ARPANSA may wish to consider providing more detail about patient identification requirements. | Noted |
| 6 | Geraldine Robertson | 309 | 3.1.5 | By whom? | Changed "has been approved" to "has been authorised by the radiological medical practitioner" (see 3.1.8-3.1.11) |
| 345 | ACPSEM | 309 | 3.1.5 | More information need to explain what is meant by approved and what evidence is required to demonstrate compliance. | Approved -> has been authorised by the radiological medical practitioner (see 3.1.8-3.1.11) |
| 413 | QLD DoH | 310 | 3.1.6 | Requires clarification in situations where radiologists are not directly involved in the procedure, such as cardiologist performing interventional procedures in Cath lab. Currently dose for the procedures is documented and appropriate measures are undertaken without involvement of the radiologist. | The radiological medical practitioner is the clinician responsible for the procedure, which would be the cardiologist in this case. The Responsible Person (management license holder) has to have procedures in place. |
| 60 | Peter Williams / Len Potapof | 311 | 3.1.6 | Including “deterministic effects” in the Glossary would be useful. | Agree (used definition from IAEA GSR Part 3) |
| 202 | Diagnostic Imaging Accreditation Scheme | 312 | 3.1.7 | Patient death It is unclear what the activity exemption level is. | Exemption levels for all nuclides are outlined in Schedule 4 of the National Directory for Radiation Protection. Note that 3.1.7 is maintaining the current requirements in RPS 14: 3.1.32 |
| 414 | QLD DoH | 312 | 3.1.7 | “the relevant activity exemption level in situ:..”; should the exemption level activity be documented here for reference? | Exemption levels for all nuclides are outlined in Schedule 4 of the National Directory for Radiation Protection. Guidance can be included in a Safety Guide. Local rules can be developed from such guidance. |
| 86 | Anonymous | 313 | 3.1.7 | Not sure of the practicality of removing unsealed radioactive material from a corpse. | The requirement is that ‘consideration be given to …’. The only realistic scenario is the excision of the thyroid of a deceased patient who had received I-131 therapy shortly prior to their death, though this would also involve issues of occupation protection for staff performing such a procedure. Family consent is also relevant here. Note that 3.1.7 is maintaining the current requirements in RPS 14: 3.1.32 |
| 296 | WA Radiological Council | 313 | 3.1.7 | The responsibility for systems in place in the event of the death of a patient having undergone radionuclide therapy that currently exist in need to be addressed in the MEC. ARPANSA feedback when raised previously is that it will be covered in the safety guide. This needs to be incorporated into the MEC as it must remain a requirement not a recommendation. | The existing requirements (RPS14: 3.1.32) are in the MEC at 3.1.7. |
| 386 | ADIA | 313 | 3.1.7 | The Code should specify the activity exemption level. | Disagree. Exemption levels for all nuclides are outlined in Schedule 4 of the National Directory for Radiation Protection. |
| 203 | Diagnostic Imaging Accreditation Scheme | 317 | 3.1.7 | Patient death Would suggest that asking for mandatory removal of temporary sources would likely increase dose to medical staff. Would it not be safer to leave in situ and allow the radiation levels to decay to a safe level? At minimum suggest that a risk assessment is carried out before removal of the source. Suggest removal of clause (b) and edit to clause (c) to remove ‘permanent’. | 3.1.7 (b) matches existing requirement in RPS 14 3.1.32 (b) and applies to temporarily implanted sources and applicators. 3.1.7 (c) removed 'permanent' |
| 387 | ADIA | 317 | 3.1.7 (b) | Asking for mandatory removal of temporary sources is likely to increase dose to medical staff. It might be safer to leave in situ and allow the radiation levels to decay to a safe level. The Code could require that at a minimum, risk assessment is carried out before removal of the source. | 3.1.7 (b) matches existing requirement in RPS 14 3.1.32 (b) and applies to temporarily implanted sources and applicators. |
| 388 | ADIA | 318 | 3.1.7 (c) | ADIA suggests removing the word “permanent”. | Agree |
| 346 | ACPSEM | 322 | 3.1.7 (e) | Should these written instructions be provided by a medical physicist? Having had this circumstance arise, the most appropriate person to issue instructions would be a medical physicist. | Requirement on the Responsible Person (management license holder) is to have processes in place. Guidance on providing instructions can be included in a Safety Guide |
| 154 | Australian Society of Medical Imaging and Radiation Therapy (ASMIRT) | 324 | 3.1.8 | Line 324: Radiological Medical Practitioner – expand definition in glossary to include protected titles. | Disagree, needs to be general |
| 204 | Diagnostic Imaging Accreditation Scheme | 325 | 3.1.8 | Procedure approvals It should be noted in the code that the approval of the exposure can be a standing approval based on policy/protocol. It is not reasonable (nor do I think intended) to ensure each and every exposure is reviewed and approved individually. | Noted |
| 271 | Victorian Department of Health and Human Services | 325 | 3.1.8 | Radiological Medical Practitioner 3.1.8 Comment: the word "procedure" is considered more than just a radiological image, it is something more. Can we include the word "examination"? | The word ‘examination’ is too narrow to cater for the intent of this clause. Could use ‘examination or procedure’ but it seems unnecessary. |
| 383 | ADIA | 325 | 3.1.8 | Radiologists are required to approve a radiological procedure. This could be interpreted as requiring individual approval for all procedures, when standing approval based on policy/protocol is appropriate in many cases. Individual approval would again increase the radiologist workload substantially, with minimal safety benefits for patients. | Sites will usually have protocols. Ultimate responsibility lies with the radiological medical practitioner – Staff actually reviewing should pass questionable or complex referrals or those that don’t fit the protocol on to the relevant radiological medical practitioner |
| 389 | ADIA | 325 | 3.1.8 | The Code should make clear that approval of exposure can be a standing approval based on policy/protocol. It is not reasonable or practicable to require each exposure to be individually reviewed and approved. | Noted |
| 272 | Victorian Department of Health and Human Services | 326 | 3.1.8 (a) | 3.1.8a "Authorised by the relevant regulatory authority" - is this a good idea? People may assume that the Radiological Medical Practitioner/Radiologists would already be licensed. It was also noted authorisation doesn't have to mean licensing, can be via other means. Recognition could be through the professional bodies. Is AHPRA registration enough? | This is a matter for consideration by jurisdictions informed by professional medical specialist advice. Authorisation of a procedure is not the same as licensing a person to use radiation. The person who authorises a procedure must be sufficiently qualified to make the justification assessments and have sufficient skill and expertise to properly interpret the images made. |
| 347 | ACPSEM | 326 | 3.1.8 (a) | Clarification need: Who is the radiological medical practitioner appropriately authorised by? | By the relevant regulatory authority (see 3.1.8 (a)) |
| 205 | Diagnostic Imaging Accreditation Scheme | 331 | 3.1.8 (d) | Information on procedures Suggest that the term ‘provide’ is too strong, should use ‘make available’. Many patients are very low risk and there is little benefit in mandating that radiation information be provided. All providers should make this information available. | Agreed. Changed to 'make information on the benefits and risks associated with the procedure available to…'. This is in line with DIAS requirements and RANZCR practice standards. |
| 348 | ACPSEM | 331 | 3.1.8 (d) | This states that the radiological medical practitioner must provide information on benefits and risks. This seems to conflict with 3.1.1(d) where for diagnostic procedures the explanation does not necessarily have to be given (if not practical or requested by the patient). Is this a requirement for all radiological examinations? What scientific evidence supports observable effects in individual adults at low radiation exposures used for diagnostic imaging (<50mSv). This appears to be a move backward in terms of the risk associated with many common X-ray procedures. How is this risk to be communicated and what evidence is required for regulatory compliance. Is there a potential danger of applying, incorrectly, risk descriptors e.g. effective dose for individual patient exposure? How can the risk be determined without the expert advice from Diagnostic Medical Physicists skilled in patient dosimetry and radiation risk; as described in International Best Practice including GSR3? | Changed to 'make information on the benefits and risks associated with the procedure available to…'. This is in line with DIAS requirements and RANZCR practice standards. |
| 390 | ADIA | 331 | 3.1.8 (d) | ADIA suggests replacing “provide” with “make available”. Many studies are low-risk and there is little benefit in mandating that radiation information be provided. All providers should make radiation information available to patients. | Agreed. Changed to 'make information on the benefits and risks associated with the procedure available to…'. This is in line with DIAS requirements and RANZCR practice standards. |
| 415 | QLD DoH | 331 | 3.1.8 (d) | “A radiological medical practitioner who approves a radiological procedure must provide information on the benefits and risks associated with the procedure to the patient or patient’s legal authorised representative”; this statement isn’t practical for all radiological examinations, given radiological examinations occur 24/7. This statement should specify which procedures, such as interventional procedures and invasive procedure the radiologist is directly involved in performing. This statement should include a statement such as “depending on the nature of the procedure and the patient”. | Changed to 'make information on the benefits and risks associated with the procedure available to…'. This is in line with DIAS requirements and RANZCR practice standards. |
| 155 | Australian Society of Medical Imaging and Radiation Therapy (ASMIRT) | 334 | 3.1.9 | Line 334: expand to include “diagnostic or therapeutic radiological procedure” | The definition of 'radiological procedure' covers both diagnostic and therapeutic procedures so it is unnecessary to expand the statement as suggested. |
| 156 | Australian Society of Medical Imaging and Radiation Therapy (ASMIRT) | 334 | 3.1.9 | Line 334-346: Is it assumed that these are delegated responsibilities from the radiation medical practitioner? Diagnostic imaging requests are not routinely viewed by the radiologist. At the point of delivery, particularly line 336, 337, 341, 342, 344 and 346 are undertaken by the medical radiation practitioner. | Sites will usually have protocols. Ultimate responsibility lies with the radiological medical practitioner – refer decisions that don’t fit the protocol |
| 190 | Diagnostic Imaging Accreditation Scheme | 334 | 3.1.9 | Health status Standard 2.2, Consumer Consent and Information Standard requires that practice staff obtain and record relevant information about the patient’s health status and individual patient risk factors prior to a service being undertaken. Pregnancy and breast feeding status are included in those matters. | Noted |
| 391 | ADIA | 334 | 3.1.9 | The Code should make clear that consultation by the radiological medical practitioner is not required for every examination, which is not practical in most settings. ADIA notes that it is important to recognise the role of the medical radiation practitioner in determining the net benefit to the patient, as they are usually the party responsible for the exposure and have immediate access to the data listed in this section. | Noted. |
| 206 | Diagnostic Imaging Accreditation Scheme | 335 | 3.1.9 | Procedure justification Add in ‘and medical radiation practitioner…must take into account’. It is important to recognise the role of the MRP in determining the net benefit to the patient as they are usually the party responsible for the exposure and have immediate access to the data listed under 3.1.9. | This section is outlining the responsibilities of the radiological medical practitioner (and largely copies the existing requirements in RPS 14 3.2.1-3.2.11) Responsibility for the operator (usually MRP) is addressed in 3.1.20 MRP can raise issues with the radiological medical practitioner as per practice protocols |
| 416 | QLD DoH | 346 | 3.1.9 (h) | “In determining… any medical data and patient records relevant to the medical exposure.”; in current Australian healthcare environment, it is not possible to share Medical Imaging information across different providers particularly if patient does not want to disclose, this needs to be worded differently to accommodate where patient “opts out” from sharing this information. | Revised text to “Any available…” |
| 133 | Glenn Gillett | 347 | 3.1.10 | 3.1.10 Agree that the written referral requires: adequate patient identifying information; the clinical question to be answered; the referrer’s contact details. Suggested addition: The above details must be provided in a legible format. | Noted (see also Medicare notes about the form of a request: Note IN.0.1 as of 1 July 2018) |
| 157 | Australian Society of Medical Imaging and Radiation Therapy (ASMIRT) | 347 | 3.1.10 | Line 347: It is important to understand that justification of a medical exposure is a responsibility that is shared, in a collaborative manner, between the radiation medicine practitioner and the medical radiation practitioner. The responsibility of the medical radiation practitioner is mandated by the MRPBA and is referenced in the document – Professional capabilities for medical radiation practice. The majority of referrals for medical imaging examinations involving ionising radiation are not reviewed by a radiological medical practitioner prior to the patient being exposure to radiation. | Noted. Sites will usually have protocols. Ultimate responsibility lies with the radiological medical practitioner – refer decisions that don’t fit the protocol |
| 208 | Diagnostic Imaging Accreditation Scheme | 347 | 3.1.10 | Requesting There should be an exemption to the requirement for a request for exposures self-determined by the Radiological Medical Practitioner. Why would a person in a health screening program be exempt from the requirement for a request? It is still important that these patients have medical oversight. It is not uncommon for screening patients to discover serious incidental conditions that requires follow-up with the requesting clinician. | Screening programs are justified on a population basis. Referral is not necessary. A client will usually have a letter of invitation and only needs to demonstrate that they meet the parameters of the screening program, there is no need for an individual justification of the exposure. |
| 273 | Victorian Department of Health and Human Services | 347 | 3.1.10 | 3.1.10 Clarification: This part echoes the written referral. If the medical practitioner is also the referrer then it indicates that the information would otherwise be recorded in the medical records. Immigration chest scans don’t come from a referrer. RPS14 includes medico legal scan, the new Code does not. If the screening process not for medical purposes (unlike a medical screening program) then it would be under the Planned Exposure Code. | Comment noted. In the case of immigration chest scans, the justification case has been undertaken at the governmental level and so the processes are varied accordingly. |
| 392 | ADIA | 347 | 3.1.10 | The word “written” should be removed, as there are occasions where verbal requests are appropriate. ADIA notes that it is not possible for radiology providers to mandate that all referrals contain the information in this section. | Verbal requests must be documented The information listed is the minimum necessary to be able to determine that a procedure is justified. |
| 158 | Australian Society of Medical Imaging and Radiation Therapy (ASMIRT) | 350 | 3.1.10 (a) | Line 350: Referrals are made to radiation oncologists. Requests are made for diagnostic procedures. There is a distinction between these two terms. There is a difference according to Medicare. Requests and Referrals are not the same thing. Medicare has expiry dates and requirements for Referrals that don’t apply to Requests for imaging. Requests don’t expire but are still accepted “at the discretion of the imaging site” based on clinical information provided. Referrals have expiration dates based on who the referrer is e.g. Specialist referral is 3 months, GPs may refer for a fixed period or indefinitely. It is not uncommon to receive a Request form for a patient that needs an exam to be performed more than 12 months from the original signing of the Request. This “discretion” is as part of the ARPANSA required Justification process. Every Request for imaging already needs to be ‘Justified’ by the radiologist before being undertaken. | Changed 3.1.10 to request, but still describe the requesting practitioner as a "referrer" |
| 209 | Diagnostic Imaging Accreditation Scheme | 350 | 3.1.10 | Requesting There are occasions where verbal requests are suitable and the term ‘written’ should be removed. | Documentation is necessary |
| 210 | Diagnostic Imaging Accreditation Scheme | 350 | 3.1.10 | Requesting Note that this is a change in terminology. Earlier in the document this is called a ‘Request’. We should ensure that the document is consistent throughout and if possible aligned with MBS (i.e, Request, Requestors rather than Referral, Referrers) | Changed 3.1.10 to request, but still describe the requesting practitioner as a "referrer" |
| 211 | Diagnostic Imaging Accreditation Scheme | 350 | 3.1.10 | Requesting It will not be possible for imaging providers to mandate that each referral contains this information. Whilst all strive for best practice scenario it is unreasonable at this stage for the information to be a hard requirement. | The information listed is the minimum necessary to be able to determine that a procedure is justified. |
| 7 | Geraldine Robertson | 351 | 3.1.10 (a) | Define in glossary, stating what they should include. OR state here DOB, Name, address Medicare number etc | Not the role of the Code to state the specific identifying elements needed in a referral |
| 207 | Diagnostic Imaging Accreditation Scheme | 351 | 3.1.10 (a) | Patient identification Consider including in the Glossary a definition of patient identification information. | This is information that would be included in a Safety Guide, not the Code. |
| 191 | Diagnostic Imaging Accreditation Scheme | 358 | 3.1.11 | Prescription, referral Standard 2.1, Provision of Service Standard reflects the current legislative requirements regarding requested and self-determined diagnostic imaging services. The terms prescription, referral and specification are used interchangeably in Clause 3.1.11 and the footnote in the draft Code. In a Medicare context, the more correct terminology relating to diagnostic imaging procedures would be a ‘request’ and not a ‘referral’. There are other sections in the Code where the term referral is used. It may be beneficial to clarify these terms in the Code, perhaps in the Glossary. Regulation 19 in the Health Insurance Regulations 1975 sets out the information which must be included in a request for a Medicare-funded diagnostic imaging service. It is important to note that certain allied health practitioners are also permitted to request certain Medicare-funded diagnostic imaging services. | Noted. Procedure prescriptions (radiotherapy) and procedure specifications (diagnostic radiology and nuclear medicine) are descriptions of procedures, they are not the same as the referral for imaging (request) or treatment. The footnote is intended to indicate that requests and procedure prescriptions or specifications can be in an electronic form. |
| 212 | Diagnostic Imaging Accreditation Scheme | 358 | 3.1.11 | Usability Using the term ‘prescription’ is likely to be confusing for consumers as it has a pharmacy connotation. | Prescription OK for therapy |
| 8 | Geraldine Robertson | 360 | 3.1.11 (a) (i) | Another name for a referral? Confusing as the consumer associates this with a Pharmacy script. | No this is not another name for a referral. A therapeutic dose is prescribed |
| 159 | Australian Society of Medical Imaging and Radiation Therapy (ASMIRT) | 360 | 3.1.11 (a) (i) | Line 360, line 363, line 367: Does this include electronic prescriptions and instructions? If so, include (electronic) | Yes, see footnote |
| 160 | Australian Society of Medical Imaging and Radiation Therapy (ASMIRT) | 361 | 3.1.11 (a) (ii) | Line 361 and Line 368: Is “have provided generic written guidelines for the procedure” meant to assume that there are protocols in place for the procedures? | Yes |
| 393 | ADIA | 362 | 3.1.11 (b) | ADIA considers it unreasonable to mandate that all nuclear medicine studies require an individual written prescription. Doses are outlined in practice protocols, and are either set doses for the study or a weight-based dose. | An approved practice protocol meets the requirements of this clause, as was already the case for the existing clause RPS14:3.2.4(b) Reword as per diagnostic or interventional procedure ‘specify in writing the procedure to be performed, or have provided generic written guidelines for the procedure’ |
| 32 | Penny Hill - ACT | 363 | 3.1.11 (b) (i) | specification of a diagnostic nuclear medicine procedure  ‘and’ or ‘or'? | Original copied directly from RPS 14 3.2.4 (b) Reword as per diagnostic or interventional procedure ‘specify in writing the procedure to be performed, or have provided generic written guidelines for the procedure’ |
| 213 | Diagnostic Imaging Accreditation Scheme | 363 | 3.1.11 (b) | Requesting It is unreasonable to mandate that all nuclear medicine studies require an individual written prescription. Doses are outlined in practice protocols and are either set doses for the study or a weight based dose. | Agree, modify Reword as per diagnostic or interventional procedure ‘specify in writing the procedure to be performed, or have provided generic written guidelines for the procedure’ |
| 214 | Diagnostic Imaging Accreditation Scheme | 367 | 3.1.11 (c) | Requesting It is unreasonable to mandate that the radiologist would have to specify the examination to be performed by the MRP. For example, if a patient presents for a chest x-ray? [Cough] Is this really saying that the MRP would need to take the request to the radiologist who would need to ‘specify in writing’ that a PA and Lateral are required? | Specify the procedure or provide generic written guidelines (protocols) |
| 191 | Diagnostic Imaging Accreditation Scheme | 358 | 3.1.11 | Prescription, referral Standard 2.1, Provision of Service Standard reflects the current legislative requirements regarding requested and self-determined diagnostic imaging services. The terms prescription, referral and specification are used interchangeably in Clause 3.1.11 and the footnote in the draft Code. In a Medicare context, the more correct terminology relating to diagnostic imaging procedures would be a ‘request’ and not a ‘referral’. There are other sections in the Code where the term referral is used. It may be beneficial to clarify these terms in the Code, perhaps in the Glossary. Regulation 19 in the Health Insurance Regulations 1975 sets out the information which must be included in a request for a Medicare-funded diagnostic imaging service. It is important to note that certain allied health practitioners are also permitted to request certain Medicare-funded diagnostic imaging services. | Noted. Procedure prescriptions (radiotherapy) and procedure specifications (diagnostic radiology and nuclear medicine) are descriptions of procedures, they are not the same as the referral for imaging (request) or treatment. The footnote is intended to indicate that requests and procedure prescriptions or specifications can be in an electronic form. |
| 394 | ADIA | 367 | 3.1.11 (c) (i) | ADIA considers this requirement to be excessive. It is not necessary, for example, for medical radiation practitioner to take a request for a chest x-ray to the radiological medical practitioner, who would then specify in writing that a PA and lateral is required. | An approved practice protocol meets the requirements of this clause, as was already the case for the existing clause RPS14:3.2.4(c)(i) |
| 417 | QLD DoH | 369 | 3.1.11 (c) (iii) | “In approving…have provided generic written guidelines for the procedure.”; all radiographers “medical imaging technologists” are trained healthcare professionals with training in all radiological procedures, departments do have protocols in place defining the requirements but do not have generic written guidelines for the procedure in detail and it does not seem to be appropriate to be writing another text book for procedures. | A practice protocol that indicates the necessary procedural requirements to an operator fulfils the requirement for "generic written guidelines". |
| 19 | David Thiele | 370 | 3.1.12 & 3.1.13 3.1.22 & 3.3.3 | Sections 3.1.12, 3.1.13, 3.1.22, 3.3.3 appear to say similar things and perhaps should be consolidated. | 3.1.12 and 3.1.13 outline responsibilities for the radiological medical practitioner, 3.1.22 is for the operator and 3.3.3 is the overarching responsibility for the responsible person to have procedures in place to determine pregnancy status. |
| 215 | Diagnostic Imaging Accreditation Scheme | 370 | 3.1.12 | Radiation dose and pregnancy Perhaps this should first require that patients of childbearing age are asked about pregnancy status? | Addressed in 3.3 |
| 349 | ACPSEM | 370 | 3.1.12 & 3.1.22 | Inconsistent wording. Both would be best written with reference to the abdomen dose rather than a foetal dose as the female is of childbearing capacity and not necessarily pregnant. Similarly, 3.2.13(e) mentions abdomen or pelvis. It would be better to be consistent throughout – either refer to abdomen and pelvis routinely or just abdomen. | Agreed. Changed wording of 3.1.22, 3.2.13, and 3.3.3 to match that of 3.1.12. Referred to uterus throughout |
| 395 | ADIA | 370 | 3.1.12 | ADIA suggests that the Code require providers to ask patients of childrearing age about pregnancy status. | The requirement on the business (see 3.3.3) is to have procedures in place to ascertain pregnancy status. There are additional requirements on the radiological medical practitioner (3.1.12) to ensure that reasonable steps are taken to determine pregnancy and on the operator (3.1.22) to confirm or establish pregnancy status. |
| 9 | Geraldine Robertson | 374 | 3.1.12 (a) | (proposed addition) or could be pregnant | Disagree. We don’t think the addition is necessary. |
| 61 | Peter Williams / Len Potapof | 375 | 3.1.12 (b) | This clause is currently restricted to therapeutic nuclear medicine. The testing for pregnancy must also be carried out for radiotherapy treatment. | Disagree. As with any radiological procedure, reasonable steps must be taken to establish pregnancy status before radiotherapy treatment. Requirement for a definitive biochemical test only necessary for therapeutic nuclear medicine procedure. |
| 71 | Tomas Kron | 378 | 3.1.13 | 3.1.13: I believe the dose calculations for a pregnant woman must be carried out by a medical physicist | Changed to 'obtain, from a medical physicist, an estimate of …'  Current Safety Guide provides generic estimates |
| 103 | Stewart Midgley | 378 | 3.1.13 | The clause does not consider the potentially pregnant patient that is unconscious or presents at the Emergency department, where the risks would be explained afterwards. | prefaced sub-clause (c) with 'except in an emergency…' |
| 274 | Victorian Department of Health and Human Services | 378 | 3.1.13 | 3.1.13 Comment: Must explain prior, in the case of an emergency situation, this would not occur. | prefaced sub-clause (c) with 'except in an emergency…' |
| 350 | ACPSEM | 384 | 3.1.13 | Communicating the risk to the referrer before the procedure is performed may be unpractical? Pregnant patient may present for procedure and referrer may not be available. In addition, is it not a requirement for all pregnant patients’ procedures to be justified individually by the radiological medical practitioner? Requirement to explain risk to referrer is valid for any procedure to be performed on a patient who, unknown to the referrer, is pregnant. How can the effective dose be determined for a given procedure without expert advice from Medical Physicists, skilled in patient dosimetry and radiation risk; as described in international best practice GSR3? | The text matches the existing requirements in RPS 14 Schedule B. Amended to remove requirement to explain risks in the case of an emergency |
| 10 | Geraldine Robertson | 386 | 3.1.13 | (proposed addition) (e) Obtain written consent | Agree |
| 88 | Anonymous | 386 | 3.1.13 (d) | Should be done by a medical physicist. | Changed to 'obtain, from a medical physicist, an estimate of …'  Current Safety Guide provides generic estimates |
| 351 | ACPSEM | 386 | 3.1.13 | How is the foetal dose to be recorded? How can the expected radiation dose be determined without the expert calculations performed by Medical Physicists skilled in patient dosimetry; as described in International Best Practice GSR3? | Changed to 'obtain, from a medical physicist, an estimate of …'  Current Safety Guide provides generic estimates |
| 418 | QLD DoH | 386 | 3.1.13 (d) | “Where a…. estimate and record the expected radiation dose to the embryo or foetus.”; this requires medical physicist to do the calculation and Radiographer and or Radiologists may not be in a position to do this. | Changed to 'obtain, from a medical physicist, an estimate of …'  Current Safety Guide provides generic estimates |
| 20 | David Thiele | 387 | 3.1.14 & 3.3.4 | Sections 3.1.14, 3.3.4 appear to say similar things and perhaps should be consolidated. | 3.1.14 is the responsibility of the radiological medical practitioner to ensure that dose to a breast-feeding infant is eliminated or minimised. 3.3.4 is the overarching responsibility for the responsible person to have procedures in place to determine breast-feeding status |
| 419 | QLD DoH | 393 | 3.1.16 | This clarification required is in the same line with the prior described situation in 3.1.6. Additionally, “liaise with the referrer to ensure follow-up of the patient.”- this statement does not give clear interpretation of what effects of radiation and what could be done. | The radiological medical practitioner is the clinician responsible for the procedure, which may be a radiologist, cardiologist, vascular surgeon, or other clinician. The requirement is to inform the patient’s referring practitioner of the possibility of subsequent deterministic radiation effects so that the referrer would be aware of this possibility if the patient subsequently presents with skin irritations or other symptoms that might result from a high radiation dose. A definition of deterministic effects has been added to the Glossary. |
| 33 | Penny Hill - ACT | 394 | 3.1.16 | radiation-induced | Disagree |
| 72 | Tomas Kron | 396 | 3.1.17 | ‘Immediately available’ may require more clarification. | Change to “The radiological medical practitioner must be immediately available in person while a High Dose Rate (HDR) brachytherapy radiation source is within the patient, for all procedures where medical assistance could be required to remove a source-containing applicator from the patient in the event of an emergency.” |
| 89 | Anonymous | 396 | 3.1.17 | 3.1.17 ‘immediately available’. This needs to be stronger. The radiation oncologist must be in the control room during HDR. This may suggest that they just need to be contactable. | Change to “The radiological medical practitioner must be immediately available in person while a High Dose Rate (HDR) brachytherapy radiation source is within the patient, for all procedures where medical assistance could be required to remove a source-containing applicator from the patient in the event of an emergency.” |
| 420 | QLD DoH | 396 | 3.1.17 | Change current proposed wording: “The radiological medical practitioner must be immediately available in person while a radiation source is within the patient, for all High Dose Rate (HDR) brachytherapy procedures where medical assistance could be request to remove a source-containing applicator from the patient in the event of an emergency.” to: “The radiological medical practitioner must be immediately available in person while a High Dose Rate (HDR) brachytherapy radiation source is within the patient, for all procedures where medical assistance could be required to remove a source-containing applicator from the patient in the event of an emergency.” This slight rewording emphasises HDR and the requirement that the radiological medical practitioner being present during the entire procedure, and makes it clear that the radiological medical practitioner does not need to be present for similar treatments such as PDR (which can take up to 24 hours) or LDR (where sources are left inside the patient permanently). | Agree. Change to “The radiological medical practitioner must be immediately available in person while a High Dose Rate (HDR) brachytherapy radiation source is within the patient, for all procedures where medical assistance could be required to remove a source-containing applicator from the patient in the event of an emergency.” |
| 161 | Australian Society of Medical Imaging and Radiation Therapy (ASMIRT) | 400 | 3.1.18 | Line 400 definition of Operator – in the glossary define who this may be i.e. radiological medicine practitioner, medical radiation practitioner, medical physicist | Operator is a functional term and could be from a range of professions. Removed the term "medical radiation technologist" and its definition from the document entirely and added a sentence to the definition of "operator", stating that: "Operators are usually medical radiation practitioners, but, depending on the context, could also be radiological medical practitioners or other persons authorised to use radiation sources for this purpose by the relevant regulatory authority." Replaced all instances of "medical radiation technologist" with "operator". |
| 216 | Diagnostic Imaging Accreditation Scheme | 407 | 3.1.20 | Consent Consider adding that the operator has advised risks to the patient and has obtained consent. | Responsibility of medical practitioner, also overall business responsibility |
| 11 | Geraldine Robertson | 408 | 3.1.20 (a) | Add somewhere that the patient is aware of the risks and benefits of the procedure and has agreed | The code assigns the responsibility of informing re risk and benefit to the radiological medical practitioner, not the operator |
| 352 | ACPSEM | 408 | 3.1.20 (a) | How is this approval provided and evidenced to ensure compliance with regulatory authorities, more detail is required? Evidencing needs to be practical, simple and cost effective (ALARP) | This is the same as the existing requirement in RPS 14 3.3.4 (a). Either the radiological medical practitioner has explicitly approved an individual procedure or has signed off on a general protocol that allows the operator to determine from the request that the procedure is justified. |
| 162 | Australian Society of Medical Imaging and Radiation Therapy (ASMIRT) | 410 | 3.1.20 (a) (ii) | Line 410-412: recommend substitution of the word “established” with the words “endorsed or established”. Contemporary clinical departments would more commonly have examination protocols developed by an inter professional group of clinicians involving medical radiation practitioners, medical physicists and radiation medicine practitioners. | Agree |
| 192 | Diagnostic Imaging Accreditation Scheme | 410 | 3.1.20 | Written protocols Standard 3.1, Diagnostic Imaging Protocol Standard requires a practice to have documented protocols for the acquisition of optimised images. The requirements for written protocols in the draft Code are broadly consistent with the requirements in Standard 3.1. | Noted |
| 217 | Diagnostic Imaging Accreditation Scheme | 410 | 3.1.20 | Procedure approval This wording resolves some of the issues noted in the responsibilities in sections 3.1.8-3.1.17. Suggest that this wording is used above for clarity. | 3.1.8-3.1.17 are responsibilities of the radiological medical practitioner. 3.1.18-3.1.27 are the responsibilities of the operator. Usually these are different persons, though they can be the same person in some circumstances. |
| 163 | Australian Society of Medical Imaging and Radiation Therapy (ASMIRT) | 421 | 3.1.20 (e) (iii) | Line 421: suggest that “monitoring” would be a more appropriate word than “oversight” | Agree |
| 73 | Tomas Kron | 428 | 3.1.22 | 3.1.22: I am not sure if the operator is in a position to determine doses as accurate as 1mSv – this would be the task of a medical physicist | Noted. This could be documented advice in the form of a technique chart with associated dose estimates. The Safety Guide (RPS 14.1) gives general guidance in Annex A |
| 218 | Diagnostic Imaging Accreditation Scheme | 428 | 3.1.22 | Radiation dose and pregnancy Suggest that checking pregnancy status should be point number 1 on this topic. | Retaining the existing wording from RPS 14 3.3.6. If the procedure has been individually approved by the radiological medical practitioner, then the operator would confirm that pregnancy status has been established. In the more routine case where the operator has performed the justification in line with practice protocols, it becomes the operator's responsibility to take reasonable steps to establish pregnancy status. |
| 421 | QLD DoH | 432 | 3.1.22 (b) | “take reasonable steps to establish the pregnancy status of the patient.”; a definition of ‘reasonable steps’ should be included. | Guidance is presently given in the Safety Guides and will be included in any future revision or update of the Guides. |
| 90 | Anonymous | 434 | 3.1.23 | 3.1.23 ‘administration’. Could be taken to mean a non-clinical area e.g. an office. | Noted. Change to ‘radiopharmaceutical administration’. |
| 125 | Glenn Gillett | 434 | 3.1.23 | 3.1.23 radionuclide administration area | Change to 'radiopharmaceutical administration'. |
| 242 | Sam Towns | 434 | 3.1.23 | Section 3.1.23 line 434 – change or further define ‘administration’, could be misconstrued as a reception area rather than where drugs are administered. | Change to ‘radiopharmaceutical administration’. |
| 250 | Anonymous | 434 | 3.1.23 | Clarify/define the term "administration" (3.1.23) | Change to ‘radiopharmaceutical administration’. |
| 275 | Victorian Department of Health and Human Services | 434 | 3.1.23 | 3.1.23 Clarification: the reference to "administration" is probably intended to refer to the area of delivery not an office area. | Change to ‘radiopharmaceutical administration’. |
| 12 | Geraldine Robertson | 443 | 3.1.25 | What are these? | Safety devices that are designed to prevent initiation of an exposure when the necessary protective barriers are not in place. |
| 324 | RANZCR | 443 | 3.1.25 | Please state the steps that the operator should take if such bypass occurs during routine use of the equipment. For example, to whom should this be reported? If inadvertent exposure to ionising radiation were the result, what steps should be taken? | See 3.1.26 and 3.1.27, operator who experiences a fault must cease use, record details, report to radiological medical practitioner and Responsible Person (management license holder) |
| 91 | Anonymous | 445 | 3.1.26 | 3.1.26. Requires better definition. Some equipment may have restriction, but are perfectly safe to use of other procedures whilst awaiting repair. | Existing text maintains current requirements in RPS 14: 3.3.10 |
| 13 | Geraldine Robertson | 453 | 3.1.27 | State how? Verbally and in writing? | Reporting must be as outlined in the Radiation Management Plan |
| 219 | Diagnostic Imaging Accreditation Scheme | 453 | 3.1.27 | Radiation incident reporting Consider clarifying the form of reporting required (i.e. would verbal reporting be sufficient for this purpose?). | Facility to specify in their management plan |
| 353 | ACPSEM | 454 | 3.1.27 (a) | Provisions should allow integration into organisation / facilities non-ionising (or other ionisation radiation) radiation incident management documentation and systems. I.e. In the Radiation Management Plan links, utilises, other documentation | The requirement is that the operator report any unintended or accidental exposure in accordance with the procedures set out in the Radiation Management Plan. The Radiation Management Plan may link or refer to other documents (see Schedule A, A.2) |
| 220 | Diagnostic Imaging Accreditation Scheme | 456 | 3.1.27 | Radiation incident reporting There may be occasions when an exposure occurs and there is no single radiological medical practitioner to report to. Suggest that reporting to the responsible person is sufficient. | Reporting to the responsible person is not sufficient for the purposes of this code – it would be if the incident is only an equipment-related matter which did not affect patients at all (refer to the Planned Exposure Code). Otherwise, the matter will be a health matter and the report should be made to an authorised person and preferably the practitioner who authorised the procedure |
| 396 | ADIA | 456 | 3.1.27 (b) | There may be occasions when an exposure occurs and there is no single radiological medical practitioner to report to. ADIA suggests that reporting to the Responsible Person is sufficient. | Reporting to the responsible person is not sufficient for the purposes of this code – it would be if the incident is only an equipment-related matter which did not affect patients at all (refer to the Planned Exposure Code). Otherwise, the matter will be a health matter and the report should be made to an authorised person and preferably the practitioner who authorised the procedure |
| 164 | Australian Society of Medical Imaging and Radiation Therapy (ASMIRT) | 458 | 3.2.1 | Line 458: Justification of medical exposure: This is in the current version of the code but is not stressed. ASMIRT are pleased to see more emphasis given to justification. | Noted |
| 277 | Victorian Department of Health and Human Services | 463 | 3.2.2 | 3.2.2 Clarification: This is a form of delegated justification. Sites are encouraged to provide instruction, usually to a radiographer, for when the patient presents. The communication component is provided when the written referral has enough information for the operator to make the decision whether it fits. Comment: The evidence required to do this is different in other states. Common pathways would be preferred. Comment: A list of all clinically accepted procedures is a big job and is a lot to expect individual sites to do this work and constantly "reinventing the wheel". Is this something that RANZCR or another body can do? | Noted. The professions and regulators will find ways of meeting the requirements of the code more repeatably. These types of efficiency improvement are to be expected, but they must meet the requirements of the code. |
| 34 | Penny Hill - ACT | 464 | 3.2.2 | move ‘either’ into option (a) | Disagree |
| 354 | ACPSEM | 464 | 3.2.2 | What is does depending on the nature of the procedure and the patient, mean? Ok if this referring to a local decision process; otherwise more detail is required in particular see below: Who is the authority? The clinical medical exposure experts are e.g. RANZCR, ACPSEM, ASMIRT. Requirements appears to use language direct from IAEA international best practice, where most member States typically have a single recognised authority who utilised the expert advice of the professional bodies to provide a unified approach for that country. | The text is the same as the existing requirement in RPS 14 3.1.3 (a) Reworded for simplicity. Removed “depending on the nature of the procedure and the patient” |
| 14 | Geraldine Robertson | 465 | 3.2.2 (a) | What does this mean? Explain | Generic justification by a radiological medical practitioner consists of providing routine indications for delegated staff to assess justification. A professional college may also provide such routine indications. |
| 221 | Diagnostic Imaging Accreditation Scheme | 465 | 3.2.2 | Procedure justification This wording resolves some of the issues noted in the responsibilities in sections 3.1.8-3.1.17. Suggest that this wording similar to the term ‘generic’ authorisation is used in these sections for clarity. | Changed “generically” to “generically, via a written protocol authorised by a radiological medical practitioner for the procedure”. |
| 15 | Geraldine Robertson | 468 | 3.2.3 | All these require the information to be provided on the referral. How can this be achieved? | The referral must contain all the necessary information |
| 134 | Glenn Gillett | 468 | 3.2.3 | 3.2.3 justification, communication - Perhaps this clause could be reworded to something like “The Responsible Person must have processes in place to ensure that the justification of medical exposure for an individual patient is provided by the radiological medical practitioner, with or without communication undertaken with the referrer as appropriate, with account taken, in particular for patients who are pregnant or breast-feeding or are paediatric, of: " The aim of the rewording is to make communication between the RMP and referrer more on an as required basis, rather than more of a mandatory basis. | As indicated in relation to 3.1.1 (above), communication includes the information on the referral. If the referral provides sufficient detail the radiological medical practitioner can perform the justification without any further communication with the referrer. |
| 165 | Australian Society of Medical Imaging and Radiation Therapy (ASMIRT) | 468 | 3.2.3 | Line 468-476: Is there an assumption that this is protocolised? The majority of imaging requests are not sighted by the radiologist before the imaging is performed. | Yes |
| 222 | Diagnostic Imaging Accreditation Scheme | 468 | 3.2.3 | Requesting In order to comply, it appears that a providing practitioner will require considerably more information in a request form from a requesting practitioner, than is currently required. Consideration needs to be given to how to ensure the requester provides the expected information. | It might be helpful if sample request forms are provided in a safety guide or bulletin provided by a professional body such as the RANZCR. |
| 223 | Diagnostic Imaging Accreditation Scheme | 468 | 3.2.3 | Requesting Unsure what this is trying to achieve in practice? Is this simply stating that there needs to be a request form and medical report to book the procedure? | It is stating that there needs to be a written request form and is providing an expectation of the minimum suite of information required on the request form. It is implying that, without this minimal information the irradiation of the patient cannot be justified. |
| 302 | WA Radiological Council | 468 | 3.2.3 | Specifics have been lost e.g. >1mSv to a breast-fed child | Addressed by 3.3.3 & 3.3.4 |
| 355 | ACPSEM | 469 | 3.2.3 | Communication with the referrer, as appropriate, is ambiguous and present compliance issues, in particular evidencing compliance to satisfy Regulatory Authorities interpretation. Unless the spirit of this requirement is to ensure the responsible person/radiological medical practitioners have systems of control governed by internal decision processes. | Referral constitutes communication. If the referral doesn’t contain sufficient information, further communication may be necessary. The Responsible Person is required to have policies and procedures in place that ensure this happens (no procedure without referral, contact referrer if referral doesn’t contain sufficient information, etc.) |
| 166 | Australian Society of Medical Imaging and Radiation Therapy (ASMIRT) | 470 | 3.2.3 | Line 470: May be referral or as previously noted, may be a request. This is particularly pertinent if the request is not recent. | Continue to use 'referrer' as the defined term. |
| 276 | Victorian Department of Health and Human Services | 478 | 3.2.4 | 3.2.4 Radiation Protection for medical exposure Justification Clarification: Referral guidelines is mentioned here. Other bodies are currently looking at ways to adopt such mechanisms therefore may change in the future. | Noted. |
| 397 | ADIA | 478 | 3.2.4 | ADIA considers it inappropriate to mandate alignment to international referral guidelines, as these are not always accepted by the Australian medical community. By including this in the Code, medical practitioners may be medico-legally exposed for appropriately delivered services which the patient later argues did not meet a foreign standard. | The requirement is that there are processes in place to ensure that relevant referral guidelines are taken into account. Change “… that relevant national or international referral guidelines…” to “… that relevant referral guidelines endorsed by the relevant professional body or the relevant regulatory authority…” |
| 224 | Diagnostic Imaging Accreditation Scheme | 479 | 3.2.4 | Requesting Remove ‘or international referral guidelines’. It’s not appropriate to mandate alignment to international referral guidelines as they are not always accepted by the Australian medical community. By leaving this in the standard medical practitioners may be medico-legally exposed for appropriately delivered services which the patient later argues did not meet a foreign standard. | Changed from “… that relevant national or international referral guidelines…” to “… that relevant referral guidelines endorsed by the relevant professional body or the relevant regulatory authority…” |
| 356 | ACPSEM | 479 | 3.2.4 | What are relevant national or international referral guidelines (GSR3?) and any requirements of the relevant regulatory authority? Are international guidelines in harmony with this document and regulatory requirements? The Code is made mandatory through Management Licensing arrangements, (with the exception of NSW), will local regulatory requirements sync with this Code. There is a potential to have a non-uniform approach to a very important process of the patient safety and clinical care? GSR3 justification requirements of medical exposures, is to be performed in collaboration with medical physicists – this essential role of the medical physicist in the justification process is absent from the Code? | GSR Part 3 does not contain referral guidelines. Various international colleges and societies have produced referral guidelines. Justification is a clinical consideration involving the radiological medical practitioner and the referrer. |
| 74 | Tomas Kron | 482 | 3.2.5 | 3.2.5 I think this is a good approach to screening | Noted |
| 357 | ACPSEM | 483 | 3.2.5 | Example of appropriate professional bodies should be recognised e.g. RANZCR, ACPSEM. NB. If a screening procedure is justified by the federal health authority in collaboration with professional bodies, based on clinical need and radiation risk; why is the local regulatory authority needed in the decision process? Local regulatory authorities should be strongly encouraged to seek unified expert advice about clinical and dosimetry (radiation risk) decisions from RANZCR, ACPSEM and ARPANSA. | “… and approved by the relevant regulatory authority, as appropriate.” Approval may be needed in some cases and not in others |
| 225 | Diagnostic Imaging Accreditation Scheme | 484 | 3.2.5 | Procedure justification Suggest that defined terms be bold or italic for easy reference. | Noted. |
| 251 | Anonymous | 486 | 3.2.6 | 3.2.6 is unnecessary. | The working group has decided that this clause is not necessary and has deleted it. |
| 398 | ADIA | 486 | 3.2.6 | ADIA suggests defining “health screening program”. | ‘Approved health screening program’ is defined in the glossary. |
| 422 | QLD DoH | 486 | 3.2.6 | Requires clarification as to the practicality of approving every examination on asymptomatic individuals by radiologists, particularly X-rays from clinicians. The X-rays are performed prior to the involvement of the radiologists. Systems are in place to limit CT but is not feasible to monitor every X-ray on asymptomatic individuals. | The working group has decided that this clause is not necessary and has deleted it. |
| 226 | Diagnostic Imaging Accreditation Scheme | 488 | 3.2.6 | Procedure justification Should ‘Health Screening Program’ be a defined term? | ‘Approved health screening program’ is defined in the glossary. |
| 35 | Penny Hill - ACT | 493 | 3.2.7 | Consider initial capitals as per https://www.nhmrc.gov.au/health-ethics/human-research-ethics-committees-hrecs | Agree |
| 36 | Penny Hill - ACT | 495 | 3.2.7 | Include year in citation of RPS 8 | Agree, also added RPS 8 to list of references |
| 37 | Penny Hill - ACT | 496 | 3.2.7 | NHMRC statement Updated May 2015 | Revised citation |
| 38 | Penny Hill - ACT | 498 | 3.2.7 | ‘in’->’of’ | Agree |
| 193 | Diagnostic Imaging Accreditation Scheme | 500 | 3.2 | Optimisation Standard 3.2, Optimised Radiation Technique Charts Standard requires that radiation exposure must be kept as low as reasonably achievable through the selection of equipment and techniques sufficient to provide the required clinical information. The requirements in the Code are consistent with the expectations and evidentiary requirements in Standard 3.2. | Noted |
| 279 | Victorian Department of Health and Human Services | 500 | 3.2 | Optimisation of protection and safety Calibration/ Dosimetry Clarification: the new Code now requires this of all sources, not just radiotherapy. The current Code already required that a Qualified Expert be available to consult, now require input from a Medical Physicist. Not too different in practice. | Noted. There is little different otherwise except that the person performing the task is now called a medical physicist. |
| 75 | Tomas Kron | 504 | 3.2.9 | 3.2.9 For design consideration, the Responsible Person should work in collaboration with suppliers and the medical physicist | Existing text matches requirements of GSR Part 3 |
| 252 | Anonymous | 504 | 3.2.9 | 3.2.9 requires clarification - which standards? | The standards themselves describe the equipment to which they are applicable. |
| 358 | ACPSEM | 504 | 3.2.9 | What is the standard adopted by the relevant regulatory authority; likely to be the standards around safety and equipment performance etc. Unfortunately each regulatory authority has a different standard promoting non-uniformity of safety and patient care; because the equipment performance will have direct impact on patient image quality and dose. Regulatory standards typically do not comply with international best practice and all safety requirements of IEC and ISO. This requirement is conflicting in nature. International standards of best practice are designed to ensure medical equipment (ancillary equipment) and software are fit for clinical purpose and safe for patients and staff; professional bodies who have access to an abundance of subject/domain experts, should be consulted and have direct input to these standards e.g. ACPSEM, ASMIRT, RANZCR. Mammography is one example: ACPSEM/RANZCR have developed a good standard utilising many experts in the field, based on sound science and international best practice. With the exception of NSW, relevant regulatory authorities have now adopted this standard or are/have developed their own standard without input from RANZCR or ACPSEM. Again medical physics contribution and leading roles in equipment clinical performance has not been recognised in the Code (and integration of Standards into a comprehensive QA program appears to be not well understood); International Best Practice GSR3 has been ignored. | Change to “and to any” rather than “or” so that any state or territory standard is in addition to IEC and ISO requirements. |
| 423 | QLD DoH | 504 | 3.2.9 | “The Responsible Person, in collaboration with suppliers, must ensure that medical radiological equipment and software that could influence the delivery of medical exposure….”; suppliers have an obligation to inform the Responsible Person of a hardware or software fault that may lead to an unintended exposure to a patient. This obligation should be included. | Important point but not the role of this Code. This falls under the requirements of TGA medical device regulation. |
| 119 | Kym Rykers | 511 | 3.2.10 | Modify order. (move and/or to after medical physicist) | Agree |
| 135 | Glenn Gillett | 511 | 3.2.10 | 3.2.10 Happy with the proposed wording. In particular the “and/or the medical physicist….” | Wording has been altered in response to other comments, however Involvement of given disciplines is “as appropriate” |
| 280 | Victorian Department of Health and Human Services | 511 | 3.2.10 | 3.2.10 Operational considerations Clarification: The right procedure and equipment should be used and the team should ensure that the dose is adequate to meet the clinical objective. | Noted. |
| 259 | Victorian Department of Health and Human Services | 512 | 3.2.10 | “as appropriate” and “if appropriate” is too subjective | The wording is attempting to deal with a range of possible settings. The professionals involved in any given setting will depend on the nature and types of procedures being undertaken. |
| 359 | ACPSEM | 515 | 3.2.10(b) | “with account taken of relevant norms of acceptable image quality” further clarification | Image quality should meet the requirements of the diagnostic task. Professional bodies may give guidance on such requirements (for example RANZCR runs a CT Image Review Self Audit program (https://www.ranzcr.com/fellows/clinical-radiology/quality-assurance-and-accreditation/ct) |
| 253 | Anonymous | 517 | 3.2.10 (b) | 3.2.10(b) are there "acceptable" norms? | Image quality should meet the requirements of the diagnostic task. Professional bodies may give guidance on such requirements (for example RANZCR runs a CT Image Review Self Audit program (https://www.ranzcr.com/fellows/clinical-radiology/quality-assurance-and-accreditation/ct) |
| 281 | Victorian Department of Health and Human Services | 517 | 3.2.10 | 3.2.10b Comment: In reference to account taken of relative norms of acceptable image quality. Are there any? And is this a significant gap in the Code? Is this up to the radiologist to determine? | The radiologists and their professional opinion cannot be codified. The requirements will very over time, hence the wording. Image quality should meet the requirements of the diagnostic task. Professional bodies may give guidance on such requirements (for example RANZCR runs a CT Image Review Self Audit program (https://www.ranzcr.com/fellows/clinical-radiology/quality-assurance-and-accreditation/ct) |
| 39 | Penny Hill - ACT | 520 | 3.2.10 (b) | capitalise DRLs | Agree |
| 76 | Tomas Kron | 521 | 3.2.11 | 3.2.11 I do not think the and/or in the second line is appropriate. In particular in advanced technology this must be an ‘and’ | Agree, change to ‘and’ |
| 167 | Australian Society of Medical Imaging and Radiation Therapy (ASMIRT) | 521 | 3.2.11 | Line 521- 525: In Australia, radiation dosimetry is performed by radiation therapists. It is primarily the responsibility of the radiation therapist, not the medical physicist, to ensure that “that for each patient the exposure of volumes other than the planning target volume is kept as low as reasonably achievable consistent with delivery of the prescribed dose to the planning target volume within the required tolerances.” Radiation oncologists, radiation therapists and medical physicists collaborate to ensure that this is the case, but the dosimetry is performed by the radiation therapist. The education and training of radiation therapists differs from that of other countries and as such aligning with the codes of other countries is not appropriate in this respect. | Team approach with ultimate responsibility with the clinician but a range of processes and activities in place to ensure appropriate outcome |
| 282 | Victorian Department of Health and Human Services | 521 | 3.2.11 | 3.2.11 When referencing the "Medical Physicist and/or" the "or" should be removed. The Medical Physicist should be involved in any new techniques and high risk techniques in radiotherapy. | Agree. |
| 168 | Australian Society of Medical Imaging and Radiation Therapy (ASMIRT) | 526 | 3.2.12 | Line 526-531: In Australia, the Nuclear Medicine Physician, in collaboration with the Nuclear Medicine Technologist and/or Nuclear Medicine Scientist (protected title) “ensure that for each patient the appropriate radiopharmaceutical with the appropriate activity is selected and administered, so that the radioactivity is primarily localised in the organ(s) of interest, while the radioactivity in the rest of the body is kept as low as reasonably achievable.” There may be no medical physicist present. | Don’t see a problem with what we have |
| 169 | Australian Society of Medical Imaging and Radiation Therapy (ASMIRT) | 532 | 3.2.13 | Line 532: Should acknowledge the role of the medical radiation practitioner and medical physicist i.e. ‘The radiological medical practitioner must, in collaboration with the medical physicist and/or the medical radiation technologist (practitioner), ensure that particular attention is given to …. | Agree |
| 325 | RANZCR | 532 | 3.2.13 | Relatively high doses is not defined – it should stipulate clearly the table of what doses and/or the mechanism or algorithm by which it is calculated. We suggest a link is provided to reference material that defines “relatively high doses” It is noted that some of the information is provided in other ARPANSA resources e.g. Radiation Protection Series No 14.2 provides information for point (f), maybe this should be referenced or linked. Please state what would constitute “particular attention” and how this would differ from the usual care exercised in developing scanning protocols. Far more detail is required as this is too non-specific and thus not auditable nor useful in identifying when a breach had occurred. Which isotopes and what parameters would define “relatively high dose”? | Text is identifying situations worthy of higher scrutiny, where more care should be taken. |
| 360 | ACPSEM | 532 | 3.2.13 | Particular attention has no meaning (for these relatively higher risk groups). The definition of high dose is ambiguous. International Best Practice has been ignored i.e. utilisation of Medical Physics Experts who can quantify radiation dose, risk and bridge the gap between technical and clinical requirements to establish optimal images protocols in collaboration with the imaging team has not been recognised in the Code. Potential of evidencing requirements {3.5.3 (b)} imposed by each of the different regulatory authorities must not impede the clinical expertise and recommendation of the experts (RANZCR, ACPSEM, ASMIRT); to ensure optimal clinical care for medical exposures. Potential consequences of non-medical physics involvement can have significant negative effect on patient care (will this be ALARP). | Text is identifying situations worthy of higher scrutiny, where more care should be taken.  Radiological medical practitioner has overall responsibility for the conduct of a given procedure.  This will mostly be addressed by practice protocols, which will be informed by appropriate advice. |
| 399 | ADIA | 532 | 3.2.13 | The term “relatively high doses” is ambiguous and ADIA suggests it be removed. | The term is intentionally subjective thereby allowing it to be interpreted in the appropriate context. Examples have been provided in the footnote |
| 227 | Diagnostic Imaging Accreditation Scheme | 537 | 3.2.13 | Procedure justification Clause (d) is ambiguous, suggest removal. Concerned with reference to undefined ‘certain computed tomography procedures’ in footnote. | The term is intentionally subjective thereby allowing it to be interpreted in the appropriate context. Examples have been provided in the footnote which has been modified to: The term ‘relatively high dose’ is intended to apply in a given context. Clearly, doses from therapeutic radiological procedures are included in ‘relatively high doses’, as are image guided interventional procedures. Depending on the context, the term ‘relatively high doses’ may also include doses from exposures in non-routine computed tomographic procedures and in nuclear medicine procedures involving higher activities of radionuclides. |
| 303 | WA Radiological Council | 537 | 3.2.13 (d) | Understand intent of this but inclusion in this section isn’t correct as if a procedure has been optimised it can’t be further optimised. | The clause is indicating types of procedures that merit special attention |
| 40 | Penny Hill - ACT | 538 | 3.2.13 (e) | ‘the’ -> ‘an’ | Agree |
| 77 | Tomas Kron | 545 | 3.2.14 | 3.2.14: It would be good to define ‘Calibration’ in the Glossary | Ordinary dictionary meaning applies |
| 104 | Stewart Midgley | 545 | 3.2.14 | Is welcomed providing motivation for radiation output testing with a suitable instrument with recent traceable calibration. Add a statement or recommendation for the minimum frequency for checking the calibration of the radiation measurement system. | Added ‘and is undertaken at Intervals approved by the relevant regulatory authority’ |
| 254 | Anonymous | 545 | 3.2.14 | 3.2.14 is too vague | Further detail on the expectations will be provided by the relevant professions and safety guides as required. |
| 283 | Victorian Department of Health and Human Services | 545 | 3.2.14 | Calibration 3.2.14 Comment: the phrase "appropriate quantities" and "bodies" are too vague. | Disagree, but acknowledge some guidance would be helpful e.g. from professions or via a safety guide. |
| 78 | Tomas Kron | 546 | 3.2.14 (a) | 3.2.14 (a) regulatory authority and (not or) professional bodies | Agree, change to ‘and’ |
| 361 | ACPSEM | 546 | 3.2.14 (a) | It is a new requirement for “all sources” to be calibrated. It is not clear how/who will do this in the radiology and NM context. Will this be explained in the Safety Guides? As it is, this is hard to interpret/implement. | Details may be addressed in a Safety Guide. 3.1.4(d) indicates that (in the radiology and nuclear medicine context) calibration should be done by, under the supervision of, or with the documented advice of a medical physicist |
| 79 | Tomas Kron | 548 | 3.2.14 (b) | 3.2.14 (b) calibration should be done by a medical physicist | As per GSR Part 3, sub-clauses 3.1.4 (c) and (d) indicate that for radiotherapy calibration can be done by or under the supervision of a medical physicist and for diagnostic equipment, calibration can be done by, under the supervision, or with the documented advice of a medical physicist (commensurate with the level of radiation risk) |
| 80 | Tomas Kron | 558 | 3.2.15 | 3.2.15: The term dosimetry is often used for treatment planning in radiotherapy. A clear definition may be helpful to ensure it is related to actual measurement. | Added definition of dosimetry Dosimetry - the measurement, calculation and assessment of ionising radiation doses absorbed by organs and tissues within the human body |
| 105 | Stewart Midgley | 558 | 3.2.15 (a) & (b) | 3.2.15 (a,b). The statement is weak as modern equipment for radiology now provides a measure of the amount of radiation delivered by every exposure to each patient. What is missing here? Encouragement to upgrade older equipment, tolerances for the accuracy of reported dose parameters such as DAP and DLP, and the regulatory motivation to collect this information. | Uptake of electronic dose tracking is not widespread at present. A representative dose is sufficient for common procedures. |
| 128 | Glenn Gillett | 558 | 3.2.15 | 3.2.15 dosimetry of patients - How frequently should the dosimetry for diagnostic examinations be performed? Perhaps that question could be answered in the international or national protocols. Are there any such protocols available for reference? Is there any dose calculating software available for diagnostic examinations that could be accessed by radiographers? Perhaps an application available on the ARPANSA website or State Regulatory Body websites. For the Northern Victorian company that I work for, we would have to pay for the likes of RadTest to come on site to measure and calculate dosimetry values. That cost would not be a recoverable expense from the hospital where the radiography service is provided. The small rural hospitals with X-ray equipment would probably also have to pay an external provider to measure and calculate dosimetry values. Could Health Purchasing Victoria contract suitable Medical Physicists to perform the tasks required within this code for Victorian hospitals that do not have a Medical Physicist on staff? | Technique chart for common procedures. Record of typical exposure factors plus periodic check of radiation output at known exposure factors. Could work output measurement into routine compliance testing. See also DIAS standard 3.2 (Technique Charts) |
| 170 | Australian Society of Medical Imaging and Radiation Therapy (ASMIRT) | 558 | 3.2.15 | Line 558-560: Is this intended to be for individual patients? If so it is not clear how this would be implemented. | In some cases yes. For diagnostic procedures the requirement is "typical doses for common procedures", which would usually be addressed by a technique chart. For image-guided interventional procedures the requirement is "typical doses to patients" which would derive from logging of dose metrics as required by the DIAS accreditation standards. Will look to ASMIRT and others to give advice on implementation in a safety guide |
| 228 | Diagnostic Imaging Accreditation Scheme | 558 | 3.2.15 | Dose optimisation Assume that the intention of this section is to regulate only for occasions when dosimetry is required for some reasons. E.g. deterministic injury, unplanned high exposure etc. This section reads as though dosimetry needs to be performed for all diagnostic and interventional procedures? This is impractical as the rage of doses is highly dependent on the individual exposure factors, patient habitus etc. Please clarify intention. | It is acknowledged that the practicalities of the dose monitoring arrangements need to be considered. However, it is expected that dose monitoring ought to be on-going, not sporadic. Of course, there will be variations based on a number of factors, but these factors will be able to be catered for in any analysis undertaken. Optimisation can only be undertaken in the light of this analysis. It is expected that sufficient information about each exposure is being stored to enable estimates of doses to all patients to be made. It would be unusual for imaging to occur without the collection of key parameters. |
| 362 | ACPSEM | 558 | 3.2.15 | Is the requirement for dosimetry to be performed using calibrated dosimeters e.g. DAP, how is this to be achieve for general X-ray and interventional equipment when DAP is not available? Provisions may need to be made to allow for the transition of dose aware equipment. How is the dosimetry to be determined form machine metrics like DAP? Dosimetry is a Medical Physicist speciality; internationally, unanimously Medical Physicists are the experts. International Best Practice has been ignored; consequently patient care may be sub-optimal. | Yes A calibrated output to determine incident air kerma can also be used A range of reference documents exist for inferring organ or effective dose from output metrics 3.1.4(d) indicates that such dosimetry should be done by, under the supervision of, or with the documented advice of a medical physicist |
| 400 | ADIA | 558 | 3.2.15 | This section is unclear. ADIA suggests clarifying that dosimetry is not required for all diagnostic and interventional procedures, as this is impractical because the range of doses is highly dependent on the individual exposure factors. | Requirement is to determine typical dose for common procedures |
| 424 | QLD DoH | 558 | 3.2.15 (a) | “The Responsible…. for diagnostic radiological procedures…”; not all older equipment have DAP meters - does ARPANSA suggest that all radiographic equipment requires DAP meters and all DAP readings are required to be documented; how long does the record need to be maintained and does it need to be auditable. | DAP meters are not essential. A site must have processes for establishing the x-ray output at given technique factors. (Look-up tables, measurements at standard settings, etc.) |
| 106 | Stewart Midgley | 566 | 3.2.15 (d) | 3.2.15 (d) Delivered activity = dispensed activity minus residual activity. Current practices assume the residual amount is negligible and focus on recording the dispensed activity. | Dispensed activity is sufficient for the purpose of estimating the dose to the patient. |
| 171 | Australian Society of Medical Imaging and Radiation Therapy (ASMIRT) | 568 | 3.2.16 | Line 568-578: DRL requirements for CT & NM are mandatory, however members note that it has not been well advertised by ARPANSA. They have become aware when DIAS assessors have taken a role in advertising to their DIAS clients. | Noted |
| 194 | Diagnostic Imaging Accreditation Scheme | 568 | 3.2.16 | Diagnostic reference levels In accordance with the requirements of Standard 3.2, Optimised Radiation Technique Charts Standard practices must annually compare their facility reference levels against any national diagnostic reference levels which have been established. The requirements in the draft Code and the DIAS standards are consistent. | Noted |
| 326 | RANZCR | 568 | 3.2.16 | This should be amended to include the number and type of examinations for which data should be collected in a routine audit for CT scanning, for which Australian DRLs exist. The recommendation should specify which data (e.g. DLP, CTDIvol, girth, age or what) should be collected. There should be a mandatory requirement to submit such data, as in the EU and to take remedial action and demonstrate it has been taken should doses be found to be above the established DRL for the examination. | The Code is outlining the requirement to perform comparisons with DRLs. Guidance on making a comparison can be included in a Safety Guide |
| 284 | Victorian Department of Health and Human Services | 569 | 3.2.15 & 3.2.16 | [Patient dosimetry] Diagnostic reference levels 3.2.15 [3.2.16] Comment: Do we have to establish FRLs? Comment: Would like to say 6 months for the DRL review is inconsistent with the international DRL review. It would have a huge cost impost on radiology facilities with people doing this (DRL) all the time. Some would take more than 6 months to collect the data. | In diagnostic imaging, the requirement is to establish “typical doses to patients for common procedures”. This is functionally equivalent to what ARPANSA calls a “Facility Reference Level” in the context of its DRL program. Patient dosimetry should be on-going rather than a small number of discrete large projects. The data is obtained continually and should be able to be collected and prepared for analysis continually. |
| 107 | Stewart Midgley | 570 | 3.2.16 (a) | 3.2.16 (a) DRL surveys to be conducted “at least annually”. | Noted Retained wording that DRL comparisons be undertaken "at least annually" |
| 229 | Diagnostic Imaging Accreditation Scheme | 571 | 3.2.16 | Dose optimisation Suggest that ‘at least annually’ be revised to read ‘as required by relevant national standards’. With the introduction of CT DRLs we have observed an initial reduction in dose which has now stabilised. It is low yield administrative burden to re-measure on such a frequent basis as annually when doses have been similar, stable and appropriate for 3+ years. | The intention is for the DRLs to be a moving target based on the most up-to-date information which, itself, will be based on clinical, procedural and technological improvements. As the intention is for almost continual optimisation processes to be in place, annual comparisons with DRLs should be easy to accomplish. |
| 401 | ADIA | 573 | 3.2.16 (b) (i) | This section could be interpreted to mean that a review is required for any cases which may exceed the DRL. ADIA suggests referral to facility reference levels and reviews need to be conducted after the survey. | Changed “for a given radiological procedure” to “for a given type of radiological procedure” Also expanded sub-clause 3.2.16 (b) (i) to read: "typical doses or administered activities for a representative sample of patients exceed …" |
| 230 | Diagnostic Imaging Accreditation Scheme | 576 | 3.2.16 | Dose optimisation This reads as though a review is required for any cases which may exceed the DRL. Suggest referral to facility reference levels and reviews need to be conducted after the survey. | Changed “for a given radiological procedure” to “for a given type of radiological procedure” Also expanded sub-clause 3.2.16 (b) (i) to read: "typical doses or administered activities for a representative sample of patients exceed …" |
| 16 | Geraldine Robertson | 578 | 3.2.16 (b) (ii) | And if this does not occur what are the consequences? | Compliance with the Code typically becomes a license condition and enforcement is a matter for the relevant regulatory authority. |
| 108 | Stewart Midgley | 580 | 3.2.17 | 3.2.17 Without regulations that mandate QA for radiology, this activity does not take place. | Noted |
| 129 | Glenn Gillett | 580 | 3.2.17 | 3.2.17 quality assurance program - The wording of this item is appropriate. In particular at the Melbourne public consultation of the draft code, some participants were recommending that the words “medical physicist” be repositioned as follows: “with the active participation of radiological medical practitioners, medical radiation technologists, medical physicists and, where relevant, radiopharmaceutical scientists ….” Changing the wording to make the inclusion of a Medical Physicist “mandatory” creates quite a difficulty and cost for those diagnostic x-ray departments in rural Victoria that do not have a Medical Physicist on staff. Leaving the consultation with a medical Physicist as “where relevant” is the most desirable outcome. | Involvement of medical physicist can be “by, under the supervision of, or with the documented advice of” see 3.1.4 (d) |
| 172 | Australian Society of Medical Imaging and Radiation Therapy (ASMIRT) | 580 | 3.2.17 | Line 580-585: ASMIRT is pleased to see that the code recognises that collaboration by all stakeholders is imperative. | Noted |
| 363 | ACPSEM | 581 | 3.2.17 | Quality assurance encompasses every aspect of the patient pathway in the delivery of safe and effect use of ionising radiation. There are many facets contributing to QA program especially (in the ionisation radiation field) e.g. DRLs, patient dosimetry, equipment quality control i.e. this requirement is in conflict with (or fails to recognise) other requirements in the Code (and IAEA International Best Practice). In addition, each regulatory authority has a different approach promoting non-uniformity of safety and patient care. The appropriate professional bodies should be recognised as the subject experts: ACPSEM, RANZCR, ARPANSA, ASMIRT. Collaboration between ACPSEM and RANZCR in mammography is a good example of a successful QA program; RANZCR MQAP. The International Best Practice GSR3 requirement of Medical Physicists involvement has been ignored. Another are Medical Physicists are internationally seen as taking a leading role. ? Missed Cancer in South Australia Screening Program is an example of a fractured QA program not utilising the correct health professions, including the absence of Medical Physics resourcing. | The requirement is for a system of quality assurance to be in place, as per GSR Part 3 para 3.170 and RPS14:3.1.21  “Principles established by relevant professional bodies … must be taken into account”  3.1.4(d) indicates that quality assurance should be done by, under the supervision of, or with the documented advice of a medical physicist |
| 81 | Tomas Kron | 583 | 3.2.17 | 3.2.17: A quality assurance program is part of the medical physicist’s responsibility. It should not be specified as ‘where relevant’ | Agreed, moved ‘medical physicist’ ahead of ‘where relevant’ |
| 120 | Kym Rykers | 583 | 3.2.17 | Include Medical Physicists in QA of exposure review as they are the key professional group with skillset to measure dosimetry from first principles. | Agreed, moved ‘medical physicist’ ahead of ‘where relevant’ |
| 243 | Sam Towns | 583 | 3.2.17 | Section 3.2.17 line 583 – move ‘medical physicists’ to the other side of ‘where relevant’. | Agreed, moved ‘medical physicist’ ahead of ‘where relevant’ |
| 285 | Victorian Department of Health and Human Services | 583 | 3.2.17 | Quality assurance for medical exposures 3.2.17 Comment: The existing wording puts Medical Physicists as optional. Is it possible to move them more forward? | Agreed, moved ‘medical physicist’ ahead of ‘where relevant’ |
| 364 | ACPSEM | 587 | 3.2.18 (a) (i) | It is not clear what is required here and particularly because it would usually be a medical physicist’s role to conduct these tests, but the medical physicist has not been mentioned. What are the tests that need to be performed – is this linked to DIAS requirements, or ACPSEM position papers or state compliance testing requirements? These tests are especially not conducted routinely after software changes in diagnostic imaging. Currently acceptance and commissioning as described in GSR3 is not a concept adopted by most, if any, regulatory authorities. Some regulatory authorities do include additional safety features tests. How is this requirement to be implemented, does it sync with DIAS accreditation; more detail is required. GSR3 emphasises the importance of the Medical Physicists role in acceptance testing and commissioning; The Code fails to align with GSR3 in recognising the Medical Physicists role and the importance of e.g. Equipment dosimetry; and integrating measurements into a comprehensive Quality Assurance program. Patients may receive inconsistent and sub-optimal imaging and thus care. | For diagnostic and interventional radiology 3.1.4(d) indicates that quality assurance, including 3.2.18 (a) (i) should be done by, under the supervision of, or with the documented advice of a medical physicist. |
| 365 | ACPSEM | 591 | 3.2.18 (a) (ii) | Currently regulatory authority (and DIAS accreditation) requirements require a comprehensive quality assurance program which encompasses periodical measurement of the physical parameter of medical radiological equipment. This includes, servicing, maintenance, compliance testing and radiographer testing. Radiographer testing recommendations are given by e.g. ACPSEM and RANZCR (and input from ASMRT); based on international and national medical physics expertise. In addition, there is also a plethora of updated international medical physics recommendation available. Presently, this information is only guidance and allows medical facilities to adopt up-to-date, evidenced based and relevant radiographer testing requirements. Is this changing? If so, expert advice should be sort from ACPSEM, RANZCR, ASMIRT. In agreement with GSR3 the important role of the Medical Physicist should be highlighted. | For diagnostic and interventional radiology 3.1.4(d) indicates that quality assurance, including 3.2.18 (a) (ii) should be done by, under the supervision of, or with the documented advice of a medical physicist. |
| 402 | ADIA | 591 | 3.2.18 (a) (ii) | ADIA suggests that specific references to relevant national standards or protocols would provide better instruction on how to comply with the Code. | Such guidance can be included in a safety guide. |
| 109 | Stewart Midgley | 593 | 3.2.18 (a) (iii) | 3.2.18 (a) (ii) “and periodically thereafter”. “Never” has an infinite time period, yet is not outlawed here. Suggest adopting the following: The ACPSEM recommends 1 year intervals for mammography, CT and fluoroscopy, 2 years for general radiography and up to 3 years for dental & BMD/DEXA apparatus. Causer et al (2005) ACPSEM Position Paper: Recommendations for a technical quality control program for diagnostic X-ray equipment Aust. Phys. & Eng, Sci. Med. 28 (2), 69-75 https://www.acpsem.org.au/documents/item/119 | Noted |
| 304 | WA Radiological Council | 593 | 3.2.18 (a) (iii) | Remove the word “major” | Agree |
| 366 | ACPSEM | 593 | 3.2.18 (a) (iii) & (iv) | This does not align with GSR3 and the important role a medical physicist makes in ensuring an appropriate judgment is made followed by the appropriate testing criteria; which in the interest image quality and patient safety; and in agreement International Best Practice goes beyond compliance testing | Clause is copied directly from GSR Part 3 |
| 110 | Stewart Midgley | 595 | 3.2.18 (a) (iii) & (iv) | 3.2.18 (a)(iii, iv) Noble aspirations. Take note that the DIMP Resources not currently available in radiology for equipment testing after all major repairs including software upgrades. | Measurements need not all be performed by a medical physicist. Code allows for ‘by, under the supervision of, or with the documented advice of’ for diagnostic and ‘by or under the supervision of’ in therapy |
| 367 | ACPSEM | 599 | 3.2.18 (c) | Verification of appropriate physical & clinical factors More information on how the verification process would take place needs to be provided, for instance, Who/how is meant to verify all clinical protocols. | The quality assurance program must include the use of ‘checks and balances’ to ensure that the facility’s protocols and procedures are being followed. |
| 92 | Anonymous | 608 | 3.2.18 (d) (iii) | Independent verification following software upgrades. Depends on the nature of the upgrade as to the patient risk. Large radiation therapy centres have numerous software systems. This could be a big challenge if independent calibration is required, each time. | Allow for an internal check after a software upgrade Separated out clause 3.2.18 (d) (iii) to new 3.2.18 (e) internal verification of calibrations of external beam radiation therapy units after any maintenance procedure or software upgrade that could affect protection and safety of patients Footnote: 'internal verification’ means performed by a medical physicist where neither the medical physicist nor the equipment was associated with the initial calibration. |
| 121 | Kym Rykers | 608 | 3.2.18 (d) (iii) | Remove this section. There are multiple systems which undergo software upgrades that ‘could affect protection and safety’. Clinical work would stop and become untenable if Health Services needed to wait for ‘non-affiliated national or international service’ to be available. | Allow for an internal check after a software upgrade Separated out clause 3.2.18 (d) (iii) to new 3.2.18 (e) internal verification of calibrations of external beam radiation therapy units after any maintenance procedure or software upgrade that could affect protection and safety of patients Footnote: 'internal verification’ means performed by a medical physicist where neither the medical physicist nor the equipment was associated with the initial calibration. |
| 244 | Sam Towns | 608 | 3.2.18 (d) (iii) | Section 3.2.18 line 608 – having an independent audit for each software upgrade would be too onerous. | Allow for an internal check after a software upgrade Separated out clause 3.2.18 (d) (iii) to new 3.2.18 (e) internal verification of calibrations of external beam radiation therapy units after any maintenance procedure or software upgrade that could affect protection and safety of patients Footnote: 'internal verification’ means performed by a medical physicist where neither the medical physicist nor the equipment was associated with the initial calibration. |
| 286 | Victorian Department of Health and Human Services | 608 | 3.2.18 (d) (iii) | 3.2.18 (d) (iii) What is meant by "maintenance" or "upgrade". There are many software upgrades (i.e. 3 times a year) and it would be cost prohibitive and impossible to have the national provider check the system each time. Internal verification would be possible but not feasible for the whole program. Should be relaxed. | Allow for an internal check after a software upgrade Separated out clause 3.2.18 (d) (iii) to new 3.2.18 (e) internal verification of calibrations of external beam radiation therapy units after any maintenance procedure or software upgrade that could affect protection and safety of patients Footnote: 'internal verification’ means performed by a medical physicist where neither the medical physicist nor the equipment was associated with the initial calibration. |
| 327 | RANZCR | 608 | 3.2.18 (d) (iii) | Suggest rewording as below. (e) secondary independent verification\* of calibrations of external beam radiation therapy units, including reference dose verification, non- reference dose verification, and end-to-end dose delivery verification after any major maintenance procedure or software upgrade that, in the considered view of the Responsible Person, could affect protection and safety of patients (f) maintaining records of relevant procedures and results, including documentation of work performed for repair, maintenance or modification (g) periodic checks of the calibration and conditions of operation of dosimetry equipment, reference equipment and monitoring equipment. These must be traceable to relevant national standards. \* Secondary independent means verification is performed by qualified staff that were not involved and do not initially know the result of the primary determination, using measuring equipment that was not used in the primary determination, and that is traceable to dosimetry standards by a path independent of the traceability of the primary determination path. Rationale for change: Major maintenance is often unscheduled, and facilities might usefully get the assistance of nearby centres to assist with the secondary independent verification. Scheduling ACDS would seem unnecessary in this circumstance (so long as the check is a “secondary independent verification” to do this), will cost a lot of time, and a lot of money. The wording is also changed to clarify the interpretation of “could” and who is responsible for forming this opinion. I could become the Governor General of Australia. The probability of the “could” in regulation clause should be orders of magnitude higher than the “could” in the clause "I could become the Governor General of Australia”. This concept is captured in the idea that “could” is the subjective considered judgment of a qualified responsible professional. Secondly, it would be unworkable and unwieldy if this was the judgment of a departmental official, or conceivably, an arbitrary external observer. Hence the suggested word formula. | Allow for an internal check after a software upgrade Separated out clause 3.2.18 (d) (iii) to new 3.2.18 (e) internal verification of calibrations of external beam radiation therapy units after any maintenance procedure or software upgrade that could affect protection and safety of patients Footnote: 'internal verification’ means performed by a medical physicist where neither the medical physicist nor the equipment was associated with the initial calibration. |
| 82 | Tomas Kron | 615 | 3.2.19 | 3.2.19: is this referring to external audits? | Changed from 'regular and independent audits' to 'regular reviews' with the following footnote: ‘regular review’ means a systematic, documented evaluation against standards or requirements set by relevant professional bodies or the relevant regulatory authority. |
| 130 | Glenn Gillett | 615 | 3.2.19 | 3.2.19 independent audits of the QA program - The use of the word “independent” may necessitate costly and time consuming practices. The relevant regulatory authority would need to clearly define practical and workable expectations of who can conduct an independent audit. | Changed from 'regular and independent audits' to 'regular reviews' with the following footnote: ‘regular review’ means a systematic, documented evaluation against standards or requirements set by relevant professional bodies or the relevant regulatory authority. |
| 305 | WA Radiological Council | 615 | 3.2.19 | Definition of independent provided in relation to 3.2.18 (d) and may not be applicable to 3.2.19 as defines independent as non-affiliated national or international service. | Footnote on 'independent' is intended to apply to 'independent verification' in 3.2.18, not to 3.2.19 Changed from 'regular and independent audits' to 'regular reviews' with the following footnote: ‘regular review’ means a systematic, documented evaluation against standards or requirements set by relevant professional bodies or the relevant regulatory authority. |
| 328 | RANZCR | 615 | 3.2.19 | The words “regular” and “independent” are subject to interpretation here and too loose to ensure appropriate implementation of this recommendation. | Footnote on 'independent' is intended to apply to 'independent verification' in 3.2.18, not to 3.2.19 Changed from 'regular and independent audits' to 'regular reviews' with the following footnote: ‘regular review’ means a systematic, documented evaluation against standards or requirements set by relevant professional bodies or the relevant regulatory authority. |
| 368 | ACPSEM | 615 | 3.2.19 | Audits of quality assurance program ‘Independent’ means performed by a non-affiliated national or international service. More detail required, who in Australia is recognised to perform such Audits, what is the complexity of the Audit, what are the costs. | Footnote on 'independent' is intended to apply to 'independent verification' in 3.2.18, not to 3.2.19 Changed from 'regular and independent audits' to 'regular reviews' with the following footnote: ‘regular review’ means a systematic, documented evaluation against standards or requirements set by relevant professional bodies or the relevant regulatory authority. |
| 425 | QLD DoH | 615 | 3.2.19 | “The Responsible Person must ensure that regular and independent audits...”; the footer further defines ‘independent’ as being performed by a non-affiliated national or international service. Further clarification of non-affiliated is needed. | Footnote on 'independent' is intended to apply to 'independent verification' in 3.2.18, not to 3.2.19 Changed from 'regular and independent audits' to 'regular reviews' with the following footnote: ‘regular review’ means a systematic, documented evaluation against standards or requirements set by relevant professional bodies or the relevant regulatory authority. |
| 231 | Diagnostic Imaging Accreditation Scheme | 619 | 3.2.20 | Dose optimisation Suggest that ‘dose constraints’ should be a defined term. | A definition of the term ‘dose constraint’ does appear in the glossary, however the first use of the term is not identified by bold text. This has been corrected. |
| 232 | Diagnostic Imaging Accreditation Scheme | 619 | 3.2.20 | Dose optimisation Suggest that ARPANSA provide example where the comforter or carer may be at risk of exceeding this ‘dose constraint’. I believe that in practice few operators would know what types of exposures could result in a dose of higher than 5mSv. | Revised to a dose constraint of 1 mSv per procedure for diagnostic procedures and 5 mSv per course of treatment for therapeutic procedures. The current UK guidance against the Ionising Radiation (Medical Exposure) Regulations 2017 is that a dose constraint of 5 mSv can be considered appropriate for most circumstances. It is also important to bear in mind that a dose constraint is not a limit but rather a planning tool for use in optimising appropriate protection options. Guidance can be given in a Safety Guide. |
| 41 | Penny Hill - ACT | 620 | 3.2.20 | Dose constraints (comforter/carer) Could this have values specific to (and appropriate for) the type of radiological examination or treatment episode? Or perhaps “…dose constraint of 50% of the patient dose up to a maximum of 5mSv per…” or some other percentage. | Revised to a dose constraint of 1 mSv per procedure for diagnostic procedures and 5 mSv per course of treatment for therapeutic procedures. The current UK guidance against the Ionising Radiation (Medical Exposure) Regulations 2017 is that a dose constraint of 5 mSv can be considered appropriate for most circumstances. It is also important to bear in mind that a dose constraint is not a limit but rather a planning tool for use in optimising appropriate protection options. |
| 93 | Anonymous | 620 | 3.2.20 | 3.2.20 Some patients have multiple treatments. Consideration should be given to assessing the dose constraint to carers over multiple rounds of therapies. | Noted. Revised to a dose constraint of 1 mSv per procedure for diagnostic procedures and 5 mSv per course of treatment for therapeutic procedures. The current UK guidance against the Ionising Radiation (Medical Exposure) Regulations 2017 is that a dose constraint of 5 mSv can be considered appropriate for most circumstances. It is also important to bear in mind that a dose constraint is not a limit but rather a planning tool for use in optimising appropriate protection options. |
| 403 | ADIA | 620 | 3.2.20 | ADIA suggests defining “dose constraint”. | A definition of the term ‘dose constraint’ does appear in the glossary, however the first use of the term is not identified by bold text. This has been corrected. |
| 404 | ADIA | 622 | 3.2.20 | ADIA suggests that ARPANSA provide examples where the comforter or carer may be at risk of exceeding the ‘dose constraint’. Few operators would know what types of exposures could result in a dose of higher that 5mSv. | Such guidance can be included in a Safety Guide. |
| 42 | Penny Hill - ACT | 623 | 3.2.21 | Consider initial capitals as per https://www.nhmrc.gov.au/health-ethics/human-research-ethics-committees-hrecs | Agree |
| 111 | Stewart Midgley | 623 | 3.2.21 | The HREC relies on the risk assessment letter that records which procedures are above standard care, sums their effective dose and applies the dose constraints of RPS8. The HREC uses this information to make the binary decision either fail or pass, subject to conditions. Replace “dose constraints specified or approved by a human research ethics committee on a case by case basis” With “dose constraints specified in RPS8, and approved by a human research ethics committee on a case by case basis” | It is the role of the HREC to consider the justification of the research and any dose constraints that should apply to the conduct of the exposures. The dose constraints in RPS 8 are given to guide the HREC. The Responsible Person at the facility conducting the medical exposure is required to ascertain that the exposure is part of an approved research program and to conduct the exposure in accordance with any requirements given in that approval. The HREC may approve proposals that exceed the dose constraints in RPS 8 if the expected benefits justify the risk. Seeking to apply the dose constraints from RPS 8 in such a case is not appropriate. |
| 112 | Stewart Midgley | 626 | 3.2.22 (proposed addition) | 3.2.22 Omission When assessing radiation incidents, the annual dose limit of 1 mSv for public exposure is a useful criteria for assessing their significance and reporting requirements. Consider making such a recommendation. | Disagree Setting criteria for reportable incidents is not a matter for the Code. At present, the parameters for reportable incidents are specified in Schedule 13 of the National Directory for Radiation Protection |
| 113 | Stewart Midgley | 626 | 3.2.23 (proposed addition) | 3.2.23 Omission When assessing radiation incidents with the potential to produce deterministic effects, the threshold for permanent damage (6 Gy absorbed dose to the skin) is a useful criteria for assessing their significance and reporting requirements. Consider making such a recommendation. | Disagree Setting criteria for reportable incidents is not a matter for the Code. At present, the parameters for reportable incidents are specified in Schedule 13 of the National Directory for Radiation Protection |
| 369 | ACPSEM | 627 | 3.3 | Additional requirements for specific patients Tissue reactions from high skin doses While section 3.4 adequately covers the situation of unanticipated or accidental exposures, there are instances where a likely consequence of the procedure is a dose to an organ or tissue that can lead to a tissue reaction. This might include complex procedures (such as cardiac or vascular interventions) particularly where the patient has a BMI in the obese/morbidly obese range and planned staged procedures are performed. While these cases might meet be determined to bestow a net benefit to the patient, despite the best efforts of the imaging staff involved, it is possible for PSDs (from individual or cumulative procedures) above prescribed thresholds to be encountered. Unlike RPS14, this document makes only limited direction in these cases (3.1.6 and 3.1.16) – this is a significant deficiency. Due to the increasing incidence of these cases, and the increased risk of litigation, it is important that specific direction is provided for circumstances where thresholds are or are likely to be exceeded. It is recommended that a category under 3.3 dealing with the management of cases at increased risk of tissue reaction is added. | The only requirement in RPS 14 that relates to tissue reactions is 3.1.15. Perhaps the comment is referring to the expanded information included in the Safety Guide (RPS 14.1). RPS C-5 3.1.6 is a direct copy of RPS 14 3.1.15 RPS C-5 3.1.16 adds an explicit requirement that the radiological medical practitioner liaise with the referrer for follow-up of the patient (previously this was implicit in the requirement that the Responsible Person have processes in place). The existing advice in the Safety Guide will remain. Such guidance information is not suitable for inclusion in a Code. |
| 260 | Victorian Department of Health and Human Services | 629 | 3.3.1 | “The Responsible Person must ensure that there are arrangements in place for appropriate radiation protection in cases where a female patient is or might be pregnant or is breast-feeding.” This requirement needs to be more specific. | Disagree. This code relies in large measure on a well-educated medical radiation workforce. If a regulator is incapable of discerning when certain requirements become relevant, it would be prudent for that regulator to determine what representatives from the relevant professions think is reasonable. However, the plight of the regulator and the regulated will be assisted by the production of guidance materials which will clarify which requirements apply in a circumstance. The subsequent clauses 3.3.2-3.3.4 also give more detailed requirements in relation to signage and having procedures to ascertain pregnancy or breast-feeding status. |
| 184 | Diagnostic Imaging Accreditation Scheme | 631 | 3.3.2 | Pregnancy signage The requirement in the draft Code to display signage about pregnancy and breast feeding status is not mandated in the DIAS standards. DIAS Standard 2.2. Consumer Consent and Information requires that prior to a diagnostic imaging procedure being performed, practice staff must obtain and record relevant information about a patient's health status and individual risk factors, and obtain consent for each diagnostic imaging procedure. | Noted. However this is already an existing requirement under RPS 14 3.1.18. |
| 195 | Diagnostic Imaging Accreditation Scheme | 631 | 3.3.2 | Signage relating to pregnancy and breast feeding status Standard 2.2, Consumer Consent and Information Standard requires that patients have access to information about the diagnostic imaging procedure prior to the service being performed. Additionally, the standard requires that practice staff obtain and record relevant information about the patient’s health status, including pregnancy and breast feeding status. The requirement in the draft Code for signage relating to pregnancy and breast feeding status goes beyond the current requirements in the DIAS standards. | Noted. However this is already an existing requirement under RPS 14 3.1.18. |
| 426 | QLD DoH | 631 | 3.3.2 | “The Responsible Person must ensure that illustrated signs in appropriate languages are…”; having appropriate resources to support the requirements of this clause is difficult for a paediatric imaging centre. The resources are not standardised and is a difficult subject matter for the referring clinician through to the operator. | This is already an existing requirement under RPS 14 3.1.18. Additional resources can addressed in a Safety Guide. |
| 43 | Penny Hill - ACT | 635 | 3.3.2 | add ‘either’ before colon add ‘or ‘ between sub-clauses | Agree Disagree |
| 233 | Diagnostic Imaging Accreditation Scheme | 639 | 3.3.3 & 3.3.4 | Pregnant and breastfeeding patients This should be referenced in the responsibilities of the imaging technologist and radiologist as suggested in earlier comments. | Requirements for the radiological medical practitioner are in 3.1.12 and 3.1.13. Requirements for the operator are in 3.1.22. Clauses 3.3.3 and 3.3.4 outline requirements for the Responsible Person (management license holder) to have policies and procedures in place. |
| 329 | RANZCR | 639 | 3.3.3 | “Procedures in place” is too vague to allow compliance to be determined or processes to be audited. Suggest more specificity with regard to exactly how pregnancy is to be determined or excluded in “at risk” patients undergoing procedures involving more than 1 mSv exposure to the fetus. Examples of such procedures should also be provided. | The Responsible Person (management license holder) ensures that there are policies and procedures in place, eg staff are to ask female patients if they are pregnant, include on pre-procedure checks, etc. See also 3.3.2, 3.1.12 (radiological medical practitioner), and 3.1.22 (operator) |
| 370 | ACPSEM | 639 | 3.3.3 | uses the phrase “reproductive capacity” rather than “child-bearing capacity”. It would be better to use consistent terminology. | Consistently used the term "child-bearing capacity" |
| 330 | RANZCR | 647 | 3.3.4 | “Significant” is not defined here. If this relates to breast cancer induction risk, an organ dose should be specified and some specific exam types that might confer this dose should be provided as examples. Once again, very difficult to determine compliance or audit processes designed to ensure compliances without defining this. | Noted. Requirement is to have policies and procedures in place. Guidance can be given in the Safety Guide. |
| 83 | Tomas Kron | 652 | 3.3.5 | 3.3.5: Some radionuclide procedures are repeated. Restricting dose to a single episode may expose carers and comforters to a considerable dose if repeat procedures are considered. Maybe add a sentence: “Consideration must be given to multiple procedures where applicable” | Changed from '5 mSv per treatment episode' to '5 mSv per course of treatment' |
| 245 | Sam Towns | 655 | 3.3.6 | Section 3.3.6 – I would like to see an entry relating to the release of a patient after a radionuclide has been administered to another department in the same or another hospital, for example, to a radiation oncology department. Confirmation of a procedure such as a bone scan to the receiving department would be beneficial, not just for the staff (I realise this code does not apply to occupational exposure) but for the patients who are members of the public. This would allow the staff to take precautions if necessary. | It is agreed that this would be useful, but such an instruction would necessarily be simply advice and therefore not part of a code. It is suggested such advice ought to be in a safety guide. |
| 94 | Anonymous | 658 | 3.3.6 (a) | 3.3.6 (a) The assessment of radioactivity of a patient upon discharge following radionuclide therapy, involves some assumptions and uncertainties. It is easier to estimate whether carers may exceed 5 mSv based on the external dose rate from the patient. | The Code states the requirement. Practical assessment is presently addressed by recommendations in RPS4. Recommendations and advice on compliance with the requirement will be included in future safety guides |
| 287 | Victorian Department of Health and Human Services | 658 | 3.3.6 (a) | Release of patients after radionuclide therapy 3.3.6a Comment: The establishment of radionuclide activity in the patient is difficult or will involve many assumptions. Not as easy as dose rate measurement. Also would not know what the patient would do. | The Code states the requirement. Practical assessment is presently addressed by recommendations in RPS4. Recommendations and advice on compliance with the requirement will be included in future safety guides |
| 288 | Victorian Department of Health and Human Services | 666 | 3.3.6 (b) (iii) | 3.3.6biii Comment: could be seen as insensitive | But necessary. |
| 17 | Geraldine Robertson | 668 | 3.4 | Unintended and Accidental Exposures When is, if at all, the patient or referring practitioner told of this. This must be documented in this Code. | As per 3.4.3 (e) the responsible person must “ensure that the radiological medical practitioner informs the patient or the patient's legal authorised representative, and where appropriate the referrer, of the unintended or accidental medical exposure.” |
| 44 | Penny Hill - ACT | 668 | 3.4 | ‘and’ -> ‘or’ | Disagree, IAEA GSR Part 3 uses the term ‘unintended and accidental’ |
| 289 | Victorian Department of Health and Human Services | 668 | 3.4 | Noted that RPS14 required that an incident must be investigated. The new Code uses the IAEA language on unintended exposure. | Noted. |
| 371 | ACPSEM | 670 | 3.4.1 | …operational failures of medical radiological equipment or facilities, from failures of and errors in software, or as a result of human error or the failure of processes. | Agree |
| 427 | QLD DoH | 670 | 3.4.1 | “The Responsible Person must ensure that…..from failures of and errors in software...”; Suppliers should have the obligation to declare to the Responsible Person of a failure of a hardware or software fault that may lead to an unintended exposure to a patient. | Important point but not the role of this Code. This falls under the requirements of TGA medical device regulation. |
| 95 | Anonymous | 674 | 3.4.2 (a) | 3.4.2 (a) a numerical value rather than the term ‘substantially’ would be more effective here. | Footnote indicates ‘outside the range normally expected’. In our view this is the most suitable, bearing in mind that this is triggering a local investigation that may or may not subsequently require reporting to the relevant regulatory authority. |
| 114 | Stewart Midgley | 674 | 3.4.2 | 3.4.2 meaning of “substantially greater” should be clarified. If only x2, that would include repeat exposures for radiology and mammography. The high work load for these modalities combined with typical rates for repeat exposures (ideally <2% for MG and <5% for GX) can translate to many per hour. Substantially greater than x2 or larger, would exclude repeat exposures for general radiology and mammography. | Footnote indicates ‘outside the range normally expected’. In our view this is the most suitable, bearing in mind that this is triggering a local investigation that may or may not subsequently require reporting to the relevant regulatory authority. |
| 306 | WA Radiological Council | 674 | 3.4.2 | Whole section needs to be consistent with the NDRP with regards to what constitutes an incident. Replace “promptly” with a specified timeframe as required by relevant regulatory authority. | Disagree. The NDRP defines a reportable incident, this clause is indicating events that must be investigated. Reporting is addressed by 3.4.3 (d) “Promptly” here refers to the investigation. Reporting requirements of the relevant regulatory authority are addressed by 3.4.3 (d) |
| 428 | QLD DoH | 674 | 3.4.2 | “The Responsible Person must ensure that unintended or accidental medical exposures”; it is unclear where maladministration fits into this document (e.g. patient injected and then the camera fails). | Maladministration as described in the comment is an example of equipment failure, which is captured by 3.4.2 (f) |
| 84 | Tomas Kron | 676 | 3.4.2 (a) | 3.4.2 (a) Substantially must be defined to be useful – could be defined by the regulatory authority | Footnote indicates ‘outside the range normally expected’. In our view this is the most suitable, bearing in mind that this is triggering a local investigation that may or may not subsequently require reporting to the relevant regulatory authority. |
| 290 | Victorian Department of Health and Human Services | 682 | 3.4.2 (c) | 3.4.2c Comment: What is defined as "substantially greater"? And is the footnote to this understood to be internally determined? | Footnote indicates ‘outside the range normally expected’. In our view this is the most suitable, bearing in mind that this is triggering a local investigation that may or may not subsequently require reporting to the relevant regulatory authority. |
| 291 | Victorian Department of Health and Human Services | 685 | 3.4.2 (e) | 3.4.2e Comment: Regarding the inadvertent exposure of the embryo or foetus, if this assessment won't change anything then what's the point? | The assessment might change how the next imaging procedure is undertaken. Also, this is a time when most parents and very anxious – proper assessment will help in the provision of any subsequent explanations. |
| 131 | Glenn Gillett | 691 | 3.4.3 | 3.4.3 The Responsible Person must, with regard to any unintended or accidental medical exposures investigated as required in clause 3.4.2: In Victoria the relevant regulatory authority previously required mandatory reporting of unintended or accidental diagnostic medical exposures, when the dose was above 1mSv. Must a medical physicist be used to make the dose calculation and dose distribution for an unintended or accidental diagnostic medical exposure? In principle I agree with the dose calculation being performed but in rural Victorian hospitals that do not have Medical Physicists on staff, it might be challenging to arrange for the dose calculation to be made in a timely manner. Can training be provided to rural and remote radiographers so that they can calculate exposure doses? | Investigation is an internal action. The results of an investigation must be reported to the relevant regulatory authority in accordance with that authority’s requirements (see 3.4.3 (d)) Physicist doesn’t have to be on staff, can use a consultant if needed. Regulatory authority can recognise a person as being able to perform dose calculations (see definition of Medical Physicist) |
| 173 | Australian Society of Medical Imaging and Radiation Therapy (ASMIRT) | 693 | 3.4.3 (a) | Line 693: include radiation therapists for radiation oncology unintended/accidental exposures. i.e “in the case of an unintended/accidental external beam radiation therapy or brachytherapy treatment arrange for the calculation or estimation by a medical physicist and/or radiation therapist of the doses received and the dose distribution within the patient | No, important to have an separate view when investigating an incident See also definition of medical physicist |
| 186 | Diagnostic Imaging Accreditation Scheme | 693 | 3.4.3 (a) | Dose calculations for unintended and accidental exposures The requirement for a medical physicist to perform a dose calculation or estimation report for any unintended or accidental medical exposures is more onerous than the requirements in some individual state and territory legislation. | Need a trained person Graded approach |
| 234 | Diagnostic Imaging Accreditation Scheme | 693 | 3.4.3 | Radiation incident reporting It is unreasonable to ask for a dose report for any unplanned exposure. These types of reported cost up to $1000 per event and for low risk unplanned exposures are a waste of time, money and cause undue concern to the patient. I also worry that there is not the physicist workforce available to meet this demand. | Incident reports are not a waste of time. Of course there is a cost, but there is also a cost for the person who has been incorrectly irradiated with the responsibility for that incident being borne by the person who is responsible for the incident. The discipline of writing incident reports is in place in most institutions. If it was a chemical spill or a bacteriological failure it would be normal to have an authoritative person make a risk assessment. This is no different. |
| 235 | Diagnostic Imaging Accreditation Scheme | 693 | 3.4.3 | Radiation incident reporting This requirement is more onerous than most current state/territory legislation, by requiring a medical physicist to do a dose report for any incident (noting that the terminology used in the draft Code to describe various practitioners will allow other staff to undertake this task at this stage, with medical physicists only required for more serious radiation incidents). | The Code is striving to achieve world’s best practice. Legislation is in place to cater for extreme situations and those for which professional approaches have failed. |
| 307 | WA Radiological Council | 693 | 3.4.3 (a) | Amend to add “when required by the relevant regulatory authority” | Disagree. Even incidents investigated internally but not meeting regulatory reporting requirements need a dose assessment. |
| 405 | ADIA | 693 | 3.4.3 (a) | ADIA considers it unreasonable to mandate a dose report for any unplanned exposure. These reports cost up to $1,000 per event, and for low-risk unplanned exposures are unnecessary and cause undue concern to the patient. | Incident reports are not a waste of time. Of course there is a cost, but there is also a cost for the person who has been incorrectly irradiated with the responsibility for that incident being borne by the person who is responsible for the incident. The discipline of writing incident reports is in place in most institutions. If it was a chemical spill or a bacteriological failure it would be normal to have an authoritative person make a risk assessment. This is no different. |
| 96 | Anonymous | 702 | 3.4.3 (e) | 3.4.3 (e) This should be consistent with the Australian Open Disclosure Framework. There are circumstances where informing the patient is not necessary and only causes stress to the patient. | Most such cases would be the lower level response described in the Australian Open Disclosure Framework, i.e. an acknowledgement that the procedure was not performed as intended but the likelihood of harm is minimal. |
| 236 | Diagnostic Imaging Accreditation Scheme | 702 | 3.4.3 | Radiation incident reporting This could be a task undertaken by the responsible person or the medical imaging operator depending on the severity (or not) of the event. | The person responsible and the person who has the relationship with the patient is the radiological medical practitioner. It is therefore this person who bears this responsibility. |
| 331 | RANZCR | 702 | 3.4.3 | There should be a strong obligation to inform the patient, their carer, or guardian as appropriate. Use of the wording of the IAEA standard is recommended, which says: (e) ensure that the appropriate radiological medical practitioner informs the referring medical practitioner and the patient or the patient’s legal authorised representative of the unintended or accidental medical exposure. (page 84 - https://www- pub.iaea.org/MTCD/Publications/PDF/Pub1578\_web-57265295.pdf) | We believe that our slightly altered text still achieves the same objectives |
| 406 | ADIA | 702 | 3.4.3 (e) | ADIA suggests that this task could be undertaken by the Responsible Person or medical imaging operator, depending on the severity of the event. | The radiological medical practitioner is responsible for ensuring overall protection and safety for any given medical exposure (see 3.1.4 (a)). It is therefore this person who bears the responsibility of informing the patient or legal authorised representative of the unintended or accidental exposure. |
| 372 | ACPSEM | 708 | 3.5.1 | GSR3 is explicit regarding Medical Physics involvement in radiological review as a tool to optimise practices. The words “where relevant the medical physicists…” is open to interpretation. | Delete “where relevant” |
| 63 | Peter Williams / Len Potapof | 714 | 3.5.2 | Radiopharmaceutical scientists should be specifically included in the list of health professionals listed within the brackets. | Agree |
| 122 | Kym Rykers | 714 | 3.5.2 | position of closing bracket in opening clause | Agree (editorial change) |
| 332 | RANZCR | 714 | 3.5.2 | The definition of specialised should include “and trained in the equipment used” including compliance with registration, CPD and other requirements of the appropriate professional body | Footnote indicates that “specialised” means “as acknowledged by the relevant professional body”, which incorporates registration, CPD, and any other requirements of the appropriate professional body. |
| 429 | QLD DoH | 714 | 3.5.2 | “The Responsible Person must ensure that personnel…..are specialised…”; this statement needs clarification in how a person is defined as specialised and acknowledged (e.g. MRP for CT and interventional). | Footnote indicates that “specialised” means “as acknowledged by the relevant professional body”, which incorporates registration, CPD, etc |
| 64 | Peter Williams / Len Potapof | 720 | 3.5.2 (c) | requiring the names of all relevant trained personnel be included within the radiation management plan (RMP) is unrealistic. In a large institution such as a teaching hospital the RMP would need to be changed every week. It would be more practicable if the responsible person maintains such a list separate to the RMP. The RMP could still state that such a list is maintained. | Changed text to "are named in a list maintained up to date by the Responsible Person and referenced in the facility’s Radiation Management Plan." |
| 97 | Anonymous | 720 | 3.5.2 (c) | 3.5.2 (c) It is not practical to maintain a list of all workers with a role to play in patient radiation safety in the RMP. The Victoria DHHS has an online facility that can be used to check is a worker holds a radiation use licence. List of staff and their qualifications are held with Department managers, so I don’t see the need for another list in the RMP. | Changed text to "are named in a list maintained up to date by the Responsible Person and referenced in the facility’s Radiation Management Plan." |
| 115 | Stewart Midgley | 720 | 3.5.2 (c) | 3.5.2 (c) It is not feasible to name all users within the RS manual, due to staff half-lives being shorter than the revision process. However it is reasonable to identify the departments involved and roles of people with radiation safety responsibilities. Actual list of names will always exists with the site records and service provider’s database for personal radiation monitoring records. | Changed text to "are named in a list maintained up to date by the Responsible Person and referenced in the facility’s Radiation Management Plan." |
| 123 | Kym Rykers | 720 | 3.5.2 (c) | Remove this section as maintaining a current list of Health service staff with specific duties with respect to radiation protection is too onerous. | Changed text to "are named in a list maintained up to date by the Responsible Person and referenced in the facility’s Radiation Management Plan." |
| 237 | Diagnostic Imaging Accreditation Scheme | 720 | 3.5.2 | Staff training It is not practical to maintain a list in the actual management plan. In QLD for example the plans need to be approved by QHealth and the review takes 6-9months. Suggest that this requirement be modified to require the responsible person to maintain a ‘register in paper or electronic form’ of the names and licence numbers. | Changed text to "are named in a list maintained up to date by the Responsible Person and referenced in the facility’s Radiation Management Plan." |
| 246 | Sam Towns | 720 | 3.5.2 (c) | Section 3.5.2 line 720 – maintaining a list such as this would be too onerous. | Changed text to "are named in a list maintained up to date by the Responsible Person and referenced in the facility’s Radiation Management Plan." |
| 292 | Victorian Department of Health and Human Services | 720 | 3.5.2 (c) | 3.5 Plans, training and record keeping Reviews and records 3.5.2c Comment: Concern with keeping a list with over hundreds of people. A change of location from the Radiation Management Plan may resolve this issue. | Changed text to "are named in a list maintained up to date by the Responsible Person and referenced in the facility’s Radiation Management Plan." |
| 373 | ACPSEM | 720 | 3.5.2 | This may be an unpractical requirement; especially for large organisations with staff regularly changing. Records must be kept; Organisation may have electronic records (systems). RMP should link/reference internal record keeping process. Interpretation required of “specific duties in relation to the radiation protection of patients” to establish the nature of this requirement. Records may be kept (and are required example for DIAS), but these are updated on an ongoing basis. A Radiation Management Plan is updated/reviewed less frequently. | Changed to "are named in a list maintained up to date by the Responsible Person and referenced in the facility’s Radiation Management Plan." |
| 407 | ADIA | 720 | 3.5.2 (c) | ADIA considers it unnecessary to require personnel to be listed in a Radiation Management Plan. Staff are already required to be registered to AHPRA and licenced by local regulatory authorities. In addition, DIAS accreditation requires practices to maintain a current staff register of AHPRA numbers and licences. To require this information to be kept in a Radiation Management Plan is a needless duplication of process. With staff turnover it would require regular updating which can be problematic with document control processes. ADIA suggests that the Code instead require the Responsible Person to maintain a register in paper or electronic form of names and licences numbers. | Changed text to "are named in a list maintained up to date by the Responsible Person and referenced in the facility’s Radiation Management Plan." |
| 293 | Victorian Department of Health and Human Services | 725 | 3.5.3 | Record keeping 3.5.3 Comment: "Sufficient evidence" is too vague. Records of training may not be accessible by RSO. | The record of training should be available to the RSO. The evidence required is sufficient to show that the responsible person has satisfactorily met obligations in relation to training. |
| 374 | ACPSEM | 725 | 3.5.3 | Evidence of justification and optimisation Further clarification on sufficient evidence and also the interpretation from each regulatory authorities needs to be provided. Evidencing of processes may have an operational impact. Potential consequences of non-uniform (requirements) evidencing can have significant negative effect on patient safety and additional cost implications (will this be ALARP). More detail is needed to understand what impact these requirements may have. | Regulators will look to guidance from the professions as to appropriate processes for documenting justification and optimisation in different settings. The code is setting the basic requirement that records of these activities must be kept. |
| 408 | ADIA | 725 | 3.5.3 | “sufficient evidence” is vague and subject to interpretation. ADIA suggests that ARPANSA clarify this term. | Regulators will look to guidance from the professions as to appropriate processes for documenting justification and optimisation in different settings. The code is setting the basic requirement that records of these activities must be kept. |
| 116 | Stewart Midgley | 726 | 3.5.3 (a) | Replace “The Responsible Person must keep sufficient evidence to be able to demonstrate” with “The Responsible Person must put processes in place that ensure sufficient evidence is retained to demonstrate” | Noted. Essentially all the requirements on the Responsible Person need to be addressed by putting procedures in place. The less explicit wording is being retained for simplicity. |
| 238 | Diagnostic Imaging Accreditation Scheme | 726 | 3.5.3 | Records As previously indicated self-determined exposures may not have a written request. | It is expected that such details would be kept anyway, usually in patient notes. See specific requirement in 3.1.10 which requires the radiological medical practitioner to document any self-referral with similar information as would be recorded on a third-party referral. |
| 261 | Victorian Department of Health and Human Services | 726 | 3.5.3(a) | Include a requirement that specifically requires the following information to be retained: 1. The name of the person that approved the procedure, 2. Date the procedure was approved; and 3. The details of the procedure that has been approved, or reference to a protocol that provides this information. | This is too much detail for this code. It would be preferable for such detail to be provided either in a safety guide or in a separate set of example request forms. |
| 409 | ADIA | 726 | 3.5.3 (a) | ADIA notes that exposure from a self-determined examination may not have a written request. | 3.1.10 requires the radiological medical practitioner to document any self-referral with similar information as would be recorded on a third-party referral. |
| 239 | Diagnostic Imaging Accreditation Scheme | 727 | 3.5.3 | Records What would ARPANSA suggest is sufficient evidence to state that optimisation and protection has been carried out? For instance we do not record exposure settings for each exposure – would maintaining copies of department protocols be sufficient? | It would be unusual for such information to not be recorded somewhere. This is a requirement which a responsible person might be best to discuss with the relevant regulator. |
| 308 | WA Radiological Council | 728 | 3.5.4 | Acknowledge amendment to 7 years or as specified by regulatory authority. RPS 14: 3.1.30 needs to be included in MEC | Requirements for quality program include maintenance of records including documentation of repair, maintenance and modification. See 3.2.18 (e) |
| 334 | RANZCR | 728 | 3.5.4 | Is 7 years sufficient for record keeping? Could be amended to ‘are retained for a minimum of 7 years or according to relevant legislation.’ | The existing text is equivalent. |
| 375 | ACPSEM | 728 | 3.5.4 | Record retention In the modern era is it relevant to place a limit of 7 years on the maintenance of records. Furthermore, it would be strongly recommended that there is a requirement placed for these records to be maintained electronically in a form that can be searched and analysed. | A period of 7 years is compatible with most minimum statutory requirements. The clause also includes “as otherwise specified by regulatory authorities”. The Code sets the requirement to maintain records, individual sites will select tools to achieve this commensurate with their scale and resources. |
| 45 | Penny Hill - ACT | 730 | 3.5.4 | delete ‘medical exposure’ before colon | Agree |
| 174 | Australian Society of Medical Imaging and Radiation Therapy (ASMIRT) | 738 | 3.5.4 (b) (ii) | Line 738: Again, is this for individual patients? It forms part of every radiation therapy and nuclear medicine patient record, but what about diagnostic imaging? | In some cases yes. For diagnostic procedures the requirement is "typical doses for common procedures", which would usually be addressed by a technique chart. For image-guided interventional procedures the requirement is "typical doses to patients" which would derive from logging of dose metrics as required by the DIAS accreditation standards. Will look to ASMIRT and others to give advice on implementation in a safety guide |
| 240 | Diagnostic Imaging Accreditation Scheme | 738 | 3.5.4 | Records As per comment in 3.2.15 please clarify which patients require dosimetry? | As stated in 3.2.15, for diagnostic radiological procedures the requirement is to determine typical dose for common procedures, for image-guided interventional procedures the requirement is to determine typical doses to patients, for radiotherapy doses to the target volume and to nominated organs at risk, and for nuclear medicine the radiopharmaceutical and the administered activity. It is acknowledged that the practicalities of the dose monitoring arrangements need to be considered. However, it is expected that dose monitoring ought to be on-going, not sporadic. Of course, there will be variations based on a number of factors, but these factors will be able to be catered for in any analysis undertaken. Optimisation can only be undertaken in the light of this analysis. It is expected that sufficient information about each exposure is being stored to enable estimates of doses to all patients to be made. It would be unusual for imaging to occur without the collection of key parameters. |
| 126 | Glenn Gillett | 743 | 3.5.4 (c) (i) | 3.5.4(c)(i) Information necessary for the retrospective assessment of doses – maybe can do with DR but CR no and those without requires logbook which is a lot of work. Often use AEC so wouldn’t know what the parameters are. | The information recorded should be sufficient to determine the typical dose for a procedure. A technique chart and records of periodic determination of the x-ray output for known technique factors would be sufficient for this purpose (as is already required under RPS 14 3.1.7 (a)) |
| 376 | ACPSEM | 746 | 3.5.4 (ii) | Information on image-guided interventional procedures The recording of data for interventional procedures should conform to the recommendations outlined by Miller et al ‘Quality Improvement Guidelines for Recording Patient Radiation Dose in the Medical Record’ J Vasc Interv Radiol 2004; 15:423–429 | The requirement is for “information necessary for the retrospective assessment of doses”. Specific references and guidance can be included in the Safety Guide. |
| 175 | Australian Society of Medical Imaging and Radiation Therapy (ASMIRT) | 750 | 3.5.4 (c) (iv) | Line 750-759: This implies that all plans have a Planning Target Volume (PTV). Usually this is the case due, however for some palliative cases, fields are marked and there is no PTV. For Superficial treatment, the treatment is defined by fields and there is no PTV defined. Suggest changing to ‘a description of the planning target volume or field’. | Agreed. Appended 'or field', text now reads: 'a description of the planning target volume or field' |
| 309 | WA Radiological Council | 750 | 3.5.4 (c) (iv) | Needs to address external beam radiotherapy, intra-operative radiotherapy and remote afterloading brachytherapy | Covers external beam radiation therapy and brachytherapy. Intra-operative radiotherapy will either use an external beam or an emplaced source (brachytherapy) |
| 176 | Australian Society of Medical Imaging and Radiation Therapy (ASMIRT) | 752 | 3.5.4 (c) (iv) | Line 752: The prescribed dose is not always at the centre of the PTV. Therefore the wording ‘the absorbed dose to the centre of the planning target volume’, is not relevant. Alternative wording could be ‘the absorbed dose representative of the treated volume’. | Appended 'or treated volume' Text now reads: ' the absorbed dose to the centre representative of the planning target volume or treated volume' |
| 196 | Diagnostic Imaging Accreditation Scheme | 765 | 3.5.5 & 3.5.6 | Radiation Management Plan and implementation Standard 1.3, Radiation Safety Standard requires a practice using ionising radiation equipment to demonstrate compliance with relevant state or territory radiation safety legislation which includes providing copies of radiation safety plans and evidence that the plans are reviewed at least once during the accreditation cycle. The requirements in the draft Code and the DIAS standards are consistent. | Noted |
| 377 | ACPSEM | 766 | 3.5.5 (a) | Radiation Management Plan The Radiation Management Plan should be an operational document detailing the specific protection in medical exposure requirements. The RMP should integrate with all relevant (or more detailed) facility policies and procedures. The RMP should be a unified document and when relevant act as a contents page referencing/linking to facilities Radiation Protection Policies and Procedures; ensuring optimal radiation safety and patient care. Currently, the relevant regulatory authority, require that the RMP has a different name; has a different process of approval and contain information, which may be better suited in a separate policy. | We agree with the objectives outlined for the Radiation Management Plan. The Code includes all these objectives. State and Territory regulators may give such a document a different name but the same underlying objectives will be addressed. |
| 378 | ACPSEM | 770 | 3.5.5 (c) | More information needed to specify requirements. For instance, what evidence will be required to demonstrate compliance? If necessary, RMP should be able to reference/link to local specific management and reporting documents. | The Radiation Management Plan can reference other policies and procedures (see footnote) |
| 379 | ACPSEM | 776 | 3.5.5 | Expertise The definition of qualified expert needs to be defined. | The term used is “qualified expert advice” and is used in the normal dictionary definition and does not require a separate special definition. |
| 310 | WA Radiological Council | 790 | Sched A | Acknowledge previous amendments. Comment: Some important points from RPS 14 not fully detailed such as A1.1 (b), (g) and (i). It is understood that in MEC Schedule A (o) is intended to be overarching, however, the above missed points should be stated individually. | RPS14 A1.1 (b) facility shielding, (g) licensing, (i) PPE are covered by the Planned Exposure Code RPS C-1, as they relate to public and occupational exposure and to general licensing requirements for planned exposure situations. |
| 18 | Geraldine Robertson | 791 | Sched A | Radiation Management Plan Should somewhere mention be made of its value when preparing for accreditation? | The principal reason for the plan is to manage radiation safety |
| 380 | ACPSEM | 791 | Sched A | Schedule A Radiation Management Plan Footnote 13: The Radiation Management Plan may make reference to, and utilise, other documented safety procedures and work practices. In addition, other items highlighted in this response should also make reference to, and utilise, other documented safety procedures and work practices; and policies. The term necessary background is vague? The RMP should describe in plain English, what a medical organisation does practically/operationally to comply with the Code, Acts, Regulations and relevant Standards. A common RMP approach (from each regulatory authority) is desperately needed; with build-in flexibility such that the RMP easily integrates and incorporates local medical organisational policies and procedures. Although a small number of individual e.g. equipment specific safety requirements are unavoidable; a common RMP promotes a consistent approach to radiation protection and patient safety; especially concerning standardisation around justification and optimisation processes. Consequently, a universal approach will help provide the same standard of patient care across Australia. | Noted. |
| 46 | Penny Hill - ACT | 793 | Sched A A.1 | all of, must be | Agree |
| 430 | QLD DoH | 811 | Sched A A1 (d) (v) | Schedule A Radiation Management Plan “observation of the patient throughout procedures…”; add with particular attention to the paediatric patient. | Don’t see a need to draw particular attention to this common example. |
| 127 | Glenn Gillett | 835 | Sched A.1 (k) | A.1(k) arrangements for obtaining expert advice in radiation protection - Perhaps “expert” could be defined, so that the appropriate type of person can be consulted. | See Planned Exposure Code (RPS C-1) |
| 117 | Stewart Midgley | 836 | Sched A.1 (l) | Replace “potential failures of” with “the potential for critical failures”. Consider providing examples for each modality in an appendix | Disagree. The code is stating the general requirement that the radiation management plan anticipates potential failures and includes appropriate preventative and responsive processes. Examples and guidance can be detailed in safety guides and professional practice documents. |
| 294 | Victorian Department of Health and Human Services | 836 | Sched A A.1 (l) | Radiation Management Plan Referring to section (l) of Schedule A Comment: A list of potential failures could be a very long list. Could a list be provided from the regulator to provide guidance about what this would look like? With specific examples. | No. The risk must be owned and ameliorated by the responsible person. The Schedule merely helps in identifying, in general terms, the areas where risks occur and common ways the risks are managed. It is a skeleton which must be built upon to form the radiation management plan for the responsible person. |
| 47 | Penny Hill - ACT | 850 | Sched A A.1 (m) (v) | Timeframe for reporting? | Management plan must specify arrangements for internal reporting and reporting to regulators |
| 48 | Penny Hill - ACT | 856 | Sched A A.1 (p) | At least annually? | Disagree, leave to requirements of the relevant regulatory authority |
| 333 | RANZCR | 868 | Appendix 1 | Reference to IAEA GSR Part 3 the IAEA is not hyperlinked and the reference is non - specific https://www-pub.iaea.org/MTCD/Publications/PDF/Pub1578\_web- 57265295.pdf - should be linked | Link to IAEA GSR Part 3 is included in the References |
| 49 | Penny Hill - ACT | 869 | Appendix 1 | ‘and’ -> ‘or’ | Disagree, IAEA GSR Part 3 uses the term ‘unintended and accidental’ |
| 311 | WA Radiological Council | 883 | Carers and comforters | May be a carer as part of occupation e.g. home-visiting nurse. Amend to remove “other than in their occupation” | Disagree. GSR Part 3 and MEC definition is for a volunteer “other than in their occupation”. Home-visiting nurses care for patients but their exposure is occupational exposure, not medical exposure. Family members providing care would be receiving medical exposure as carers and comforters |
| 312 | WA Radiological Council | 897 | Dose constraint | Definition not amended, but extra paragraph included. Remove “and source related”. Remove “safety for the source”. Is the intention for this to be protection from the source of radiation? | Disagree. Existing definition consistent with GSR Part 3 and the Planned Exposure Code. Can be read as protecting the source but is intended to mean that the constraint applies to dose arising from the radiation source employed in the planned exposure situation, and not to dose due to other factors (eg background radiation) |
| 50 | Penny Hill - ACT | 919 | Equivalent dose | Consistency in the use of lower case w? | Lower case w |
| 177 | Australian Society of Medical Imaging and Radiation Therapy (ASMIRT) | 934 | Health Professional | Line 934: Although not a regulated profession, medical physicists are health professionals. | Cross out “national” |
| 51 | Penny Hill - ACT | 938 | Human research ethics committee | Consider initial capitals as per https://www.nhmrc.gov.au/health-ethics/human-research-ethics-committees-hrecs | Agree |
| 313 | WA Radiological Council | 942 | Ionising radiation | Prefer RPS 14 definition but second preference is to remove “For the purposes of radiation protection” and “in biological material(s)” | Disagree. Existing definition consistent with GSR Part 3 and the Planned Exposure Code. |
| 314 | WA Radiological Council | 948 | Medical exposure | Previously commented on preference to insert “radiation” before the word “exposure” throughout document. ARPANSA feedback is that it would be assumed that exposure relates to ionising radiation. Noted however glossary needs to include the word radiation to negate possible assumptions. Exposure of carers and comforters is not medical exposure. Remove. | Definition of ‘medical exposure’ commences: ionising radiation exposure …”  Disagree. Exposure of carers and comforters is defined as medical exposure in GSR Part 3 and the Planned Exposure Code RPS C-1 |
| 85 | Tomas Kron | 953 | Medical physicist | Glossary: In times when IAEA and the International Organization of Medical Physics (IOMP) emphasize the need for certification this should be included in the definition. Reference to ACPSEM may be appropriate. At the present the definition of medical physicist (considering the ‘or’ in line 955) is much weaker than the related definition of Health Professional | Harmonised the definitions of Health professional, medical physicist, operator, and the like, in the general form of "a generic term for a health professional … recognised/authorised by the relevant jurisdiction". See also 3.1.4 (b) where a footnote has been added after '…adequately trained in the appropriate area' to indicate that this is 'as acknowledged and assessed by relevant professional and regulatory bodies'. |
| 178 | Australian Society of Medical Imaging and Radiation Therapy (ASMIRT) | 953 | Medical Physicist | Line 953: Query inclusion of the word “independently” in this definition and not in that of medical radiation practitioners. | Leave independently |
| 315 | WA Radiological Council | 953 | Medical physicist | Previous comment: Including the words “health professional” would preclude many people currently working in medical physics as the definition of a health professional requires the formal national recognition in the profession. Current comment: Definition amended differently than proposed, now onus is on regulatory authority to provide approval. Not sure this will be useful. | Removed ‘national’ from definition of Health professional |
| 144 | Australian Society of Medical Imaging and Radiation Therapy (ASMIRT) | 960 | medical radiation technologist/ medical radiation practitioner | Throughout the documents, the term medical radiation technologist should be replaced with medical radiation practitioner. This is the protected title for the nationally regulated profession, including radiation therapist, diagnostic radiographer, medical imaging technologist, radiographer, nuclear medicine scientist and nuclear medicine technologist. | Trying to use a more generic term Replaced all instances of ‘medical radiation technologist’ with ‘operator’. Amended definition of ‘operator’ to: “A generic term for a health professional who is authorised by the relevant regulatory authority to use radiation sources for radiology, nuclear medicine or radiotherapy. Operators are usually medical radiation practitioners, but, depending upon the context, could also be radiological medical practitioners or other persons authorised to use radiation sources for this purpose by the relevant regulatory authority.” |
| 179 | Australian Society of Medical Imaging and Radiation Therapy (ASMIRT) | 960 | Medical radiation technologist | Line 960: Protected title is Medical Radiation Practitioner. Change definition to ““A health professional, with education and training in medical radiation technology, competent and registered to practice as a medical radiation practitioner in one or more of the specialties of medical radiation practice, including radiation therapy, diagnostic imaging and nuclear medicine imaging” | Replaced all instances of ‘medical radiation technologist’ with ‘operator’. Amended definition of ‘operator’ to: “A generic term for a health professional who is authorised by the relevant regulatory authority to use radiation sources for radiology, nuclear medicine or radiotherapy. Operators are usually medical radiation practitioners, but, depending upon the context, could also be radiological medical practitioners or other persons authorised to use radiation sources for this purpose by the relevant regulatory authority.” |
| 316 | WA Radiological Council | 960 | Medical radiation technologist | Suggest amend to “a health professional, with education and training in medical radiation technology, competent to perform radiological procedures in one or more of the specialties of medical radiation technology with required authorisation from the relevant regulatory authority”. | Replaced all instances of ‘medical radiation technologist’ with ‘operator’. Amended definition of ‘operator’ to: “A generic term for a health professional who is authorised by the relevant regulatory authority to use radiation sources for radiology, nuclear medicine or radiotherapy. Operators are usually medical radiation practitioners, but, depending upon the context, could also be radiological medical practitioners or other persons authorised to use radiation sources for this purpose by the relevant regulatory authority.” |
| 317 | WA Radiological Council | 983 | Public exposure | Need to add ‘radiation’. | Changed definition of public exposure to “ionising radiation exposure …” |
| 54 | AMA | 996 | Radiological medical practitioner | The draft code assumes that all medical exposure to radiation occurs in radiology practices, and emphasises the role and responsibilities of radiologists. | The ‘radiological medical practitioner’ is the clinician with overall responsibility for a given procedure. This may be a cardiologist, vascular surgeon, or even in limited cases a general practitioner. In radiotherapy this will usually be a radiation oncologist and in nuclear medicine a nuclear medicine specialist or physician. |
| 145 | Australian Society of Medical Imaging and Radiation Therapy (ASMIRT) | 996 | Radiological medical practitioner | These documents use radiological medical practitioner. Glossary = protected titles are: Specialist radiation oncologist, Specialist radiologist, Specialist in nuclear medicine | Disagree, needs to be general |
| 180 | Australian Society of Medical Imaging and Radiation Therapy (ASMIRT) | 996 | Radiological medical practitioner | Line 996: Suggest aligning with AHPRA Radiation medicine practitioner | No |
| 182 | Diagnostic Imaging Accreditation Scheme | 996 | Radiological Medical Practitioner | Radiological Medical Practitioner The term 'radiological medical practitioner' which is used in the draft Code, could be confused with the term 'radiation medical practitioner' , the latter being a category of practitioners referred to in the Health Insurance Diagnostic Imaging Table Regulations and also in the DIAS standards. The latter term is intended to mean a person who is qualified in diagnostic radiography, radiation therapy and nuclear medicine technology and who is registered to practice using a protected title, such as a diagnostic radiographer or radiation therapist. | Noted RPS 14 has used “radiation medical practitioner” to refer to a clinician up to now and we are following international practice (IAEA GSR Part 3) in now using the term “radiological medical practitioner”. The DITR uses “medical radiation practitioner” to refer to a technologist as per the definitions and titles under the AHPRA. See the glossary definition of “radiological medical practitioner” |
| 187 | Diagnostic Imaging Accreditation Scheme | 996 | Radiological medical practitioner | Radiological medical practitioner Standard 1.2, Registration and Licencing Standard requires that practices provide evidence of and maintain all appropriate and current registration and/or licences to undertake diagnostic imaging procedures. The evidentiary requirements include Australian Health Practitioner Regulation Agency (AHPRA) registration information for those persons who are classified as ‘medical radiation practitioners’. In the absence of clarifying information in the Code, there may be potential for the terms ‘radiological medical practitioner’ and ‘radiation medical practitioner’ to be confused. | Noted |
| 318 | WA Radiological Council | 996 | Radiological medical practitioner | Amend to insert “with required authorisation from the relevant regulatory authority” | GSR Part 3 and MEC definition focuses on clinical competence. Compliance with licensing requirements of the relevant regulatory authority is addressed in 3.5.2 and 3.1.8 (a) |
| 118 | Stewart Midgley | 1009 | Referrer | Page 30. Definition for “referrer” Be aware that the MBS falls outside the definition of a “regulatory authority”, but provides funding rules that serve to control which health professionals can make a referral, also listing which procedures “Who may request a diagnostic imaging service The following practitioners may request a diagnostic imaging service: ·      Specialists and consultant physicians can request any diagnostic imaging service. ·      Other medical practitioners can request any service and specific Magnetic Resonance Imaging Services – see DIO. ·      A medical practitioner, on behalf of the treating practitioner, for example, by a resident medical officer at a hospital on behalf of the patient's treating practitioner. ·      Dental Practitioners, Physiotherapists, Chiropractors, Osteopaths and Podiatrists registered or licensed under State or Territory laws ·      Participating nurse practitioners and participating midwives.” See the Medical benefits Schedule book category 5, (01/01/15). page 28 | Noted |
| 181 | Australian Society of Medical Imaging and Radiation Therapy (ASMIRT) | 1009 | Referrer | Line 1009: also include definition of Request | Don’t need to |
| 241 | Diagnostic Imaging Accreditation Scheme | 1010 | Referrer | Definitions ARPANSA should make it clear that self-referral by Radiologists is acceptable. It could be interpreted that third party referral is required for all examinations which is not always necessary in the delivery of best patient care. | Self-referral by a radiologist would be unusual, but can be accommodated if the radiologist is considered a referrer (i.e. a medical practitioner who references the details of the diagnostic question being answered in the patient’s notes) and subsequently the requester and then, perhaps, the operator. The main objective is for the justification and imaging request processes to be adequately and retrievably documented. |
| 319 | WA Radiological Council | 1012 | Relevant regulatory authority | Remove “or authorities designated, or otherwise recognised” As previously suggested, the term should read “radiation regulatory authority” for clarity. Previous ARPANSA feedback stated same term used in RPS 14 which is correct however the MEC needs to refer to other to other regulatory authorities which could cause confusion. Radiation regulatory authority is more descriptive and the MEC provides the opportunity to improve this. | Existing definition consistent with the Planned Exposure Code RPS C-1. |
| 52 | Penny Hill - ACT | 1017 | Responsible person | Definition does not match the location of the number. Should the number move or the definition change? Is the definition appropriate? It refers to a body corporate. | Agree. Move footnote placement to after the words “legal person”. |
| 320 | WA Radiological Council | 1017 | Responsible person | Remove the word “prescribed” | Existing definition consistent with the Planned Exposure Code RPS C-1. |
| 321 | WA Radiological Council | 1033 | Unsealed source | Use definition from RPS 14 | Existing definition consistent with the Planned Exposure Code RPS C-1. |
| 200 | Diagnostic Imaging Accreditation Scheme | 261 and 1005 | 3.1.1 & Glossary | Definitions To align language between the MBS and the code it would be preferable if we used the word ‘Requestor’ rather than ‘Referrer’. Under justification it makes reference to ‘Request’ being necessary not ‘Referrals’. | Noted. Continue to use referrer. |
| 53 | Anonymous | General | General | When will there be a discuss [sic] on the radiation exposure to nuclear medicine technologist? | Occupational doses are addressed by the Planned Exposure Code (RPS C-1). A future revision of the Safety Guide for nuclear medicine (RPS 14.2) may canvass these matters. |
| 55 | AMA | General | Radiation safety training for clinicians | Several medical practitioner craft groups, other than radiologists, use ionising radiation – for example, cardiologists, orthopaedic surgeons, vascular surgeons and gastroenterologists. Radiologists and nuclear medical practitioners are well trained in the use and dangers of radiation in their college curricula and are examined on this issue. More didactic teaching needs to be mandated for other practitioners on the risks of radiation exposure and protection of the patient, other staff and themselves. | Clinical competence in a given speciality is the province of the relevant professional body. Adequacy of radiation protection training and authorisation (where required) is a matter for the relevant radiation regulatory authority. We agree that more didactic teaching for practitioners on the risks of radiation exposure and protection of the patient, other staff and themselves is important. We note that clause 3.5.2 (b) requires the Responsible Person to ensure that personnel meet the requirements of the relevant radiation regulatory authority for education, training and competence in radiation protection. |
| 56 | AMA | General | Referrer | In addition, equal responsibility must be placed on the requesting clinician, as on the radiologist, to inform the patient of the risks of radiation as well as the benefits. The requestor must have a high index of probability that the disease is present from both clinical and other lab findings. | The Code makes mention of the role of the referrer. The Code is principally used by radiation regulatory authorities to place requirements on facilities and persons using ionising radiation in medicine. Referring practitioners would not normally come within the scope of such authorities. |
| 57 | AMA | General | Guidelines | Imaging Wisely, released by the Royal Australian and New Zealand College of Radiologists, provides protocols and decision support systems which should be embedded into imaging requests to ensure the right test is done for the right reason for the right patient. | The Code supports the adoption of Guidelines (see 3.2.4) |
| 58 | AMA | General | Refusing requests | The radiologist must be empowered to refuse the test or suggests an alternative non-radiation or lesser radiation test – for example, ultrasound for aortic aneurysm rather than CT, or low dose CT for paranasal sinus disease rather than x-rays. | Radiological medical practitioners can refuse inappropriate requests or substitute more appropriate requests. Medicare rules generally allow for these actions, except in certain circumstances. |
| 59 | Peter Williams / Len Potapof | General | Internal links | Generally, the draft Code is structured much better than that originally provided. However, the constant referral throughout to other parts of the document makes it difficult to read as it requires the reader to constantly go forwards and backwards through the document when reading it. Whilst this issue may be difficult to resolve in the printed version ARPANSA should consider the use of hyperlinks within the electronic form of the document to make it much easier to read. | Will consider use of hyperlinks in the electronic version |
| 65 | Siemens Healthineers | General | Uniform licensing | Would like to see greater uniformity in licensing regimes across Australia Implementation of a centralised register of radiation licence holders within Australia Issues noted: Terminology differences Duration of licences Administering entity In some cases separate licensing for equipment and sources Notification requirements | National uniformity is a desirable outcome but these specific matters are not in the scope of the Medical Exposure Code |
| 66 | Tomas Kron | General | General | Overall this is a welcome and timely document. It is relatively brief and concise and addresses radiation safety through the ‘Responsible Person’. Overall, I believe the document is too unspecific in points (see comments below) and provides considerable freedom for people to address the requirements of the code. | Noted |
| 67 | Tomas Kron | General | Medical physicist | From this reviewer’s perspective in particular the role and qualifications/certification of the medical physicist has been weakened compared to the previous code. While the change of terminology from qualified expert to medical physicist is welcome and reflects the inclusion of the term by the International Labor Organization, it falls short in defining this according to international standards such as IAEA or IOMP. Leaving the decision of who is a medical physicist to the regulatory authority (line 949ff) makes this open to interpretation and at times conflicts of interest where the regulatory authority is also responsible for provision of health care. | Noted |
| 68 | Tomas Kron | General | Radiation safety officer | It is also disappointing that the Radiation Safety Officer is not mentioned at all (at least as a requirement for radiotherapy facilities) and assumed to be indirectly covered through the radiation management plan. More references to national (eg Radiation Oncology Practice Standards) and international documents would be helpful. | Noted |
| 124 | Joshua Daniel | General | Licensing | Having 30 years experience working internationally for Diagnostic Imaging Companies, I have a single radiation licence for working all around the states and territories in each country no matter where. Australia has individual licences for every state making it extremely difficult for National Techs working all around country to monitor different expiry dates for each state and pay individual fees that are not cheap. Please formulate a National Radiation Licence for all of Australia | Noted. This is an important issue for national uniformity. It is outside the scope of the Medical Exposure Code |
| 136 | Medical Radiation Practice Board of Australia | General | Purpose | The purpose of a Code In general, the role of a Code is to codify all requirements of a particular area or activity. It is our observation that radiation regulation and related policy tends to be a broad and diverse collection of instruments. Our suggestion is to consider drafting a Code that represents a complete and exhaustive statement on radiation protection in healthcare. | Noted |
| 137 | Medical Radiation Practice Board of Australia | General | General | Code of radiation protection in healthcare The Board welcomes the approach taken in the Code of underscoring the collaborative responsibility of the medical radiation team, which includes referring clinicians, the radiological medical practitioner, medical physicists, medical radiation practitioners (radiographers, nuclear medicine technologists, radiation therapists) and other licensed imaging operators. Our suggestion would be that given radiation is used in broader healthcare context, that is it’s not simply about medicine, rather it’s about radiation protection for every person ( be they patient, practitioner or the broader public) and the environment that is connected with providing healthcare services. On that basis that the Code could be more appropriately named the Code for radiation protection in healthcare. | Keeping the title "Code for Radiation Protection in Medical Exposure" |
| 138 | Medical Radiation Practice Board of Australia | General | The Responsible person | The Responsible person The role of “responsible person” as the person with overall governance and promotion of radiation safety in a facility is accepted. However the draft Code categorically assigns the role of ‘responsible person’ to medical physicist, and in doing indicates that only a medical physicist can fulfil that role. We note that the draft Code refers to Radiation Protection Series No.14 for a definition of the role and functions of a ‘responsible person’. Considering those functions and noting the proposal that a medical physicist act in the role of responsible person, it is unclear why that conclusion has been drawn. | The Code does not assign the role of ‘Responsible Person’ to a medical physicist. The Responsible Person is defined as the: ‘legal person having overall management responsibility, control over the premises and in whose name the premises would be registered if this is required’. This is the management license holder. This situation is unchanged from that under RPS 14. |
| 139 | Medical Radiation Practice Board of Australia | General | General | Enabling the broadest scope of practice The word-for-word adoption of international standards needs to be approached with some degree of caution. Any implementation should ensure that, to the extent possible, local arrangements mirror the requirements of the international standards, but is adapted to ensure regulatory arrangements are ‘fit for purpose’ in that jurisdiction or jurisdictions. The National Registration and Accreditation Scheme (NRAS) for health professions in Australia, the scheme to which the Board belongs, is premised on the concept of title protection, that is, only an appropriately qualified person may be registered in a health profession and may then use a protected title. One of the features of NRAS is that there are very few restrictions on practice1. The purpose of regulating title and not practice is to enable any registered health profession to undertake practice in their fullest scope of practice, noting that scope of practice is that for which an individual is trained and competent and otherwise competent to perform. Regulation in the healthcare sector, noting that this is what the draft Code is proposing to do, should be based in competency to perform tasks and functions, not restricting practice based on title of a profession. Regulation that seeks to restrict practice by ‘siloing’ activities along traditional professional boundaries simply creates barriers to the efficient and effective delivery of healthcare services. In developing a ‘fit for purpose’ model of regulation, our recommendation is that the role of other regulators, such as the National Boards and National Scheme be acknowledged, and consideration be given to what role these other regulators contribute, both now and in the future, to the overall system of regulation and managing the risk of harm to the public. | The definition of medical physicist in the Code is not restricted to a specific professional recognition and suitable persons can be recognised by the relevant regulatory authority as being able to perform the dosimetric calculations, radiation measurements and monitoring relevant to their area of expertise. |
| 140 | Medical Radiation Practice Board of Australia | General | Medical physicist workforce | Medical physicist workforce Any discussion of the proposals in the draft Code must consider the prevailing workforce conditions. While the Board recognises that the draft Code has adopted a graded approach to the involvement of the medical physicist and the established role this profession has in radiation therapy, the Board would caution against imposing practice restrictions where it is reasonable to anticipate they would have a significant effect on the efficient and effective delivery of healthcare services. The draft Code appears to proposes that medical radiation practitioners be supervised by medical physicists and it is unclear whether this is the intention of the draft Code, and if so what basis for such a proposal is. One of the fundamental tenets of professional regulation is that each registered professional is responsible for their own practice. Supervision of one regulated profession by another, in this case unregulated profession, is not consistent with the contemporary model of regulation and undermines the fundamental tenet of individual professional responsibility. Introducing a strict requirement for a medical physicist to be in every medical imaging facility, both public hospitals and private practice; into every nuclear medicine facility, both public hospitals and private practice, where that work is already being undertaken by other competent individuals, is likely to introduce a significant financial cost, and that cost is ultimately born by patients and the broader Australian public. Given the potential for significant cost it would also be reasonable to anticipate the proposed regulatory burden would lead to the cessation of clinical services provided by smaller clinical centres, which in turn would likely impact on rural and remote areas of Australia the hardest. The Board’s current Professional Capabilities for Medical Radiation Practice (2013, p9) outline the minimum requirements for practice in the profession and lend themselves or align with the functions performed by the ‘responsible person’. In the Board’s view there are many activities of the ‘responsible person’ that are currently being undertaken by registered medical radiation practitioners, often in addition to their usual tasks of providing clinical care for patients. It is further noted that the Code of Conduct for medical radiation practitioners, which is common to a number of other regulated health professions, imposes an obligation on registered practitioners to ensure that they • recognise and work within the limits of their competence and scope of practice, which may change over time • ensuring that they maintain adequate knowledge and skills to provide safe and effective care • when moving into a new area of practice, ensuring that they have undertaken sufficient training and/or qualifications to achieve competency in that area In our view, the proposals in the draft Code do not recognise the arrangements that currently exist to minimise risks and ensure the safety of the public; and against the backdrop of medical physicist workforce shortages, the proposals in the draft Code are likely to have a significant impact in terms of the cost and delivery of health services in all States and Territories of Australia. | The "supervision" mentioned in the Code relates to advice and guidance and is not intended to mean direct, in-person supervision of the sort that would apply between a practitioner and a trainee. The relevant specialist expertise of the medical physicist in assessing and measuring patient dose, testing and performance of equipment, and calibration must be available to the other professionals at any given facility. This may be in the form of documented advice and protocols and need not necessarily be delivered in person by an on-site medical physicist. The level of involvement of medical physicists should be commensurate with the complexity and risk of the procedures undertaken at the facility. The definition of medical physicist adopted in the Code allows existing arrangements to continue, while at the same time highlighting the role of medical physics and contributing to the maintenance of a suitably trained workforce to continue to provide this important input into the routine functioning of medical radiation facilities. |
| 141 | Medical Radiation Practice Board of Australia | General | Medical Physicist | Our suggestion While on one level it is appreciated that a medical physicist would be able to perform many of the functions for the role of ‘responsible person’, likewise there are other professions, including registered medical radiation practitioners that could undertake, and in most cases, currently do take on many of those functions. Our suggestion is that the various functions of the ‘responsible persons’ be undertaken by an individual or individuals who are competent to perform those tasks. In some metropolitan facilities, such as metropolitan hospitals and practices, the role might be properly fulfilled by either a medical physicist or medical radiation practitioner, or some combination thereof. In other centres, including remote and rural settings, that role could be fulfilled by either a medical radiation practitioner or other competent health professional. | The Code does not assign the role of ‘Responsible Person’ to a medical physicist. The Responsible Person is defined as the: ‘legal person having overall management responsibility, control over the premises, and in whose name the premises would be registered if this is required’. This is the management license holder. This situation is unchanged from that under the existing Code, RPS 14. The Planned Exposure Code (RPS C-1), which covers general requirements for all planned exposure situations, including medical exposures, also uses the same definition of the Responsible Person. The Planned Exposure Code also applies to medical facilities and covers requirements relating to protection of staff and the public, as well as general licensing requirements. It is important to draw a distinction between the responsibilities held by the Responsible Person (the management license holder) and the tasks or functions that derive from those responsibilities. It is the business owner, hospital CEO or management license holder who is the Responsible Person and who has the ultimate responsibility to ensure that a medical facility has appropriate policies and procedures in place to give effect to the requirements in the Code. However, the Responsible Person may delegate the tasks of developing, reviewing, maintaining and implementing those policies and procedures to other staff, who may come from a range of disciplines. |
| 142 | Medical Radiation Practice Board of Australia | General | Regulatory impact statement | Regulatory impact statement We note that ARPANSA has sought and received agreement from the Office of Best Practice Regulation (OPBR) that the proposed code ‘does not substantially alter existing requirements’. With respect, our view is that the draft Code proposes changes that does not reflect a contemporary approach to practice, does not properly consider current workforce capacity, and should the draft Code be implemented in its current state, would likely impose a significant financial cost to healthcare with the potential for the curtailing the provision of health services. | We disagree with the contention that the draft Code does not reflect contemporary practice or consider workforce capacity. The Code allows existing arrangements to continue, while at the same time highlighting the role of medical physics and contributing to the maintenance of a suitably trained workforce to continue to provide this important input into the routine functioning of medical radiation facilities. |
| 143 | Royal Australian College of General Practitioners (RACGP) | General | Referrals | The RACGP agrees with the premise that sufficient clinical details on request forms are vital in order to justify exposing a patient to radiation. A request form that fails to include the indication for the procedure and request for imaging should be considered inappropriate. Over-diagnosis and inappropriate radiation exposure are significant concerns to the RACGP, and it is hoped that this requirement will help to reduce unnecessary imaging requests. From a general practitioner (GP) perspective, if the particular requested test is considered inappropriate by the radiological medical practitioner or a better or safer test is available, the suggested alternative test must be discussed and agreed with the referring medical practitioner before the test is undertaken. This should be in writing and if initially communicated via telephone, documented after the fact in writing. The requesting process could be simplified and enhanced with the use of secure messaging allowing asynchronous communication that can also be documented in the patient’s clinical record. In general, the rules around who can request X-rays and scans need to be examined and tightened. Only appropriate referrers with suitable skills and knowledge should be permitted to make the imaging requests. As an example, chiropractors can currently order whole spine x-rays without providing evidence of improved patient health. | Noted. We thank you for your support |
| 146 | Australian Society of Medical Imaging and Radiation Therapy (ASMIRT) | General | Medical physicist | It is not clear how the new Code “adopts a graded approach to the level of the medical physicist”. Radiation therapists, diagnostic radiographers and nuclear medicine technologists undertake much of the dosimetry and quality assurance independently and certainly not under the supervision of a medical physicist. It is not conducted under the supervision of the medical physicist but in collaboration with them. The scope of practice for medical physicists in radiation therapy is not well established, however it is universally recognised that radiation oncologists, radiation therapists and radiation oncology medical physicists must work collaboratively in the best interests of the patient. It is also not correct that in diagnostic imaging and image guided interventional procedures that the tasks are conducted by or under the supervision of a medical physicist. ASMIRT does not agree with the statement that “ultimately, only accredited medical physicists will be performing these functions.” Unlike medical practitioners and medical radiation practitioners, medical physics is an unregulated profession. This requirement does not reflect the nature of contemporary practice. Many practices are stand alone and do not have medical physicists on site, nor do they require them to be. Medical radiation practitioners are well qualified to undertake the duties of ensuring that the Radiation Management Plan is adhered to, and conducting dosimetry and quality assurance. ASMIRT recognises that calibration is not currently within the scope of practice for medical radiation practitioners. | The draft Code uses the term ‘medical physicist’, instead of ‘qualified expert’ but allows some flexibility in the definition by allowing the relevant regulatory authority to recognise persons as being able to perform the relevant tasks according to their expertise. Thus a range of approaches may be possible: radiotherapy sites will typically have accredited physicists available, who may perform the work themselves or in conjunction with other staff such as medical radiation practitioners; large hospital departments may also have a physicist on staff, who will use their expertise to co-ordinate the work of others, review processes and procedures, and otherwise have oversight of calibration, dosimetric and quality assurance activities; a network of private radiology practices may have a physicist on staff to perform a similar co-ordination role to that of a physicist in a large hospital; smaller hospitals or practice networks may engage the services of a physicist as a consultant on an occasional basis to review programs and procedures |
| 183 | Diagnostic Imaging Accreditation Scheme | General | Request, prescription, referral, specification | Request, prescription, referral, specification The terms 'prescription, referral and specification' are used interchangeably in the draft Code to mean a request from a requesting practitioner for a diagnostic or therapeutic procedure to be performed. In relation to Medicare-funded diagnostic imaging procedures, the correct term is ‘request’. Additionally, in a Medicare context the terms request and referral have different meanings. The draft Code is also more prescriptive than Regulation 19 in the Health Insurance Regulations 1975 regarding the information that a requesting practitioner must provide in a request for a diagnostic imaging procedure. | Changed 3.1.10 to request, but still describe the requesting practitioner as a "referrer" |
| 185 | Diagnostic Imaging Accreditation Scheme | General | Medical physics expertise | Medical physics expertise There was previously a requirement for expert opinion or action to be obtained from a 'trained medical physicist'. In the draft Code, this requirement has been changed to include a 'radiation worker' as an alternative to a trained medical physicist. At their meeting, the Committee understood that this was in response to the shortage of medical physicists across Australia, and noted that remedying this shortage will not be resolved in the short term. However, the Committee wished to clarify that it was not best practice to utilise practitioners who are not the most appropriately trained for the task at hand. | The previous requirement in RPS 14 was for a “qualified expert” for “consultation on optimisation, dosimetry and quality assurance” (RPS 14 3.1.24) The new Code uses the term “medical physicist” but allows regulators to recognise persons as competent to perform the relevant tasks, rather than restricting the term to a given professional certification. RPS 14 did not include any competency requirements for the “qualified expert”. A Statement issued by the RHC in September 2012 acknowledged ACPSEM accreditations that met the requirements of “qualified expert” but still allowed regulators to recognise persons who didn’t hold such accreditations. |
| 197 | Diagnostic Imaging Accreditation Scheme | General | Overall | Usability  It would be helpful to have a diagrammatic representation of the various ARPANSA Codes referred to in the draft Code, showing their interrelationships with each other and the draft Code. | Safety Guide |
| 247 | Anonymous | General | RPS 10 | The dental exposure code RPS10 needs to be addressed in a similar review. | Noted. |
| 255 | Nigel Freeman & Thuraisamy Ravichander | General | Medical physicist | What is very encouraging is the espoused intent of APRANSA and the drafting panel to align with IAEA General Safety Requirements Part 3 and establish a nationally uniform approach, cognizant of international attempts to homogenise codes and standards. In this context the incorporation of a definition for Medical Physics is most welcome, but it is falls short in 1) Failing to maintain consistency with the IAEA (The definition is not a close match to the IAEA definition). 2) Failing to promote national uniformity (Each State jurisdiction (regulatory authority) is enabled by this code to determine who fits the Medical Physicist definition. As noted by others’ responses, national uniformity is an existing problem and is unlikely to be enhanced by the drafted definition as it stands.) 3) Failing to achieve equivalence with the definition of similar professions of “Radiological medical practitioner” and “Medical radiation technologist” which have been adapted from IAEA essentially unchanged. 4) Introducing a “circular argument” where regulatory authority may reference this Code, which in turn references the regulatory body. The above therefore weakens this Code in promoting uniform national regulatory requirements and is inconsistent with the objectives outlined in the Foreword of the Code. “Medical physicist A health professional with education and training in the concepts and techniques of applying physics in medicine and competent to practice independently in one or more of the sub-fields of medical physics or a person who has been recognised by the relevant regulatory authority as being able to perform the dosimetric calculations, radiation measurements and monitoring relevant to the person’s area of expertise.” It is strongly suggested that to address the points above, wording after “or a person…” be removed. “Medical physicist A health professional with education and training in the concepts and techniques of applying physics in medicine and competent to practice independently in one or more of the sub-fields of medical physics” It is further suggested that a definition for “competence” and assessment of competence be included in a similar way to the IAEA document. | Response to points 1 and 2: Noted and agreed, however a more gradual move towards the current IAEA position is required in Australia in order that the desired end point will eventually be reached. Response to point 3: Please note that the generalised term ‘medical radiation technologist’ has been removed from the code. Response to point 4: It is not a circular argument, rather a statement of what can be realistically tolerated at this time.  The point is noted, but is not reasonably able to be achieved across Australia at this time. Nevertheless, the direction has been set. |
| 256 | Victorian Department of Health and Human Services | General | Compliance expectations | The Victorian Department of Health and Human Services provides both its own specific comments in relation to the proposed Code and the comments of participants as recorded by the Department during an information session conducted by the Department in relation to the proposed Code. It was clear at the workshop that participants feel that there are parts of the draft Code that are of a general nature and may leave regulators having to make decisions as to what constitutes compliance with the Code. The participants reflected that, ultimately, it is regulators’ interpretations and expectations that will influence their compliance costs and efforts. Whilst we support that broad view, we also acknowledge that the position taken in the Code is probably the correct one in that it might be inappropriate to develop highly prescriptive requirements within the Code. Our preference is that when the Code is finalised, that regulators should work quickly to develop a set of compliance expectations. These expectations ought to be tested with stakeholders and ultimately resolved through a national or multi-lateral agreement between jurisdictions. | It will probably be better to wait until safety guides have been written to help clarify the expectations of the professions before launching into developing a suite of regulator-initiated expectations. |
| 267 | Victorian Department of Health and Human Services | General | definition of a "patient" | Comment: The definition of a "patient" is not in the glossary. In the context of a screening program, this person is referred to as a "client" rather than a patient. Does this need to be defined? | No. The term ‘patient’ is well understood. |
| 278 | Victorian Department of Health and Human Services | General | Referral guidelines | Comment that RANZCR is already involved in discussions over adopting existing referral guidelines. | Noted. |
| 297 | WA Radiological Council | General | Avoidance of conception | Avoidance of conception following administration with therapeutic radionuclides is not addressed in the MEC. | Added sub-clause (iv) in 3.3.6 (advice given upon release of patient). (iv) written advice on avoidance of conception, where relevant. Guidance is given in the existing nuclear medicine Safety Guide (RPS 14.2) |
| 322 | RANZCR | General | General | After careful review, it is suggested that the Code be amended to include more specific metrics of compliance with its recommendations, otherwise these recommendations cannot be implemented in the manner intended nor can they be audited appropriately. For example, a “high” dose to the lactating breast is not defined. An appropriate number and type of CT examinations to audit for comparison with relevant DRLs is not specified and the metric(s) to collect are not stated. It remains disappointing that submitting data from such an audit is not a mandatory requirement of CT licensing in Australia. The following IAEA document, by comparison, provides more useful detail relating to specific recommendations that permits design of quality control processes that can evaluate practice:  https://www-pub.iaea.org/MTCD/Publications/PDF/Pub1578\_web-57265295.pdf | The Code contains requirements, not recommendations. Some of the elements mentioned are too detailed for explicit mention in the Code and are covered elsewhere. The Code has drawn heavily on the IAEA Basic Safety Standards (IAEA GSR Part 3) but adapts as necessary to reflect Australian practice. |
| 335 | ACPSEM | General | Medical physicist | It is disappointing that the requirements for a medical physicist in Radiology, Nuclear Medicine and Image Guided Interventional procedures has been watered down. It is noted that in the Reader’s Guide, ARPANSA comments that stakeholders should be reminded that ultimately there is an intention that only accredited [sic] medical physicists will be performing the functions of a “medical physicist”. | Noted. |
| 336 | ACPSEM | General | Medical physicist | Without regulatory drivers, such as the Code and the Diagnostic Imaging Accreditation Scheme (DIAS), for example, it is a challenge to create the positions that are needed to further grow and sustain the Diagnostic Imaging Medical Physicist (DIMP) workforce. I believe that this is a missed opportunity to take the next step in ensuring safety and quality for patients in the diagnostic and interventional environment. | Noted. |
| 337 | ACPSEM | General | Medical physicist | It is also noted that the recommendation to include the accredited medical physicist requirement is from an audit report from 2011. It would be highly beneficial for the whole community if these recommendations were implemented as soon as possible. | Noted. |
| 338 | ACPSEM | General | Safety Guides | It would have been beneficial to have the Safety Guides updated and released at the same time as the Code. It will be helpful if these can be updated and released as close as possible to the implementation of the Code. The guidance from the Safety Guides has always been helpful and key to implementation of the Code. | The existing Safety Guides are adequate in the first instance but will be updated in due course. |
| 339 | ACPSEM | General | Dosimetry | IAEA GSR Part 3, goes to some effort to include definitions of terms. Some of these definitions (eg “independent verification”, “competence”) have not been included in the C-5 code. The recommendation is that the definitions of all terms from IAEA be adopted and included in C-5.    Although this may resolve some issues, other important terms such as “dosimetry” are not explicitly defined in GSR Part 3. Given the different interpretations of this term across the professions, it would assist that the term be clarified by including a definition(s) in C-5. For example radiation therapists relate carrying out computer simulation of dose distributions in a planning computer to optimise treatment design as “dosimetry”. Medical physicists interpret dosimetry as carrying out and interpreting radiation measurements to establish an accurate beam dose model for use in the planning computer; carrying out measurements/assessment/calculations to validate end-end a patient treatment delivery or diagnostic dose; measuring doses in-vivo; and calibrating/determining the dosimetric qualities of clinical radiation beams. The recommendation is that C-5 be specifically reviewed with a view to addressing the ambiguity of terms such as “dosimetry”. | IAEA GSR Part 3 definitions have been used, except where a local variation was felt to be necessary. The examples cited appear to refer to additional information given in IAEA GSR Part 3 for additional context. The statements about assessment of competence are not suitable. The definitions of health professional, medical physicist, operator, and the like, have been harmonised in the general form of "a generic term for a health professional … recognised/authorised by the relevant jurisdiction".  Added definition of dosimetry Dosimetry - the measurement, calculation and assessment of ionising radiation doses absorbed by organs and tissues within the human body   Added back RPS 14 3.1.26 and 3.1.27 on QA for therapy treatment planning as RPS C-5 3.2.19 and 3.2.20 |
| 381 | Farshid Salehzahi | General | Medical physicist | I would like to focus the attention on the role and the definition of Medical Physicist. This is important because the weight of the role and defining the responsibility for Medical Physicists are the pivotal causes for the majority of submissions to RPS C-5 draft, in particular from non-medical physicist professionals. It is important to note that Medical Physicists are not a nationally registered profession by AHPRA. It is also important to remind that Medical Physics is an academic degree, which is either pursued via the same course title or as an associated Physics degree to postgraduate level. I emphasise on the education because academic level of other professions who would see Medical Physics a simple degree which they can do part or all of their duties, do not have a clear understanding of what is involved to study Medical Physics. Additionally, it is not well appreciated what is involved to become a practising Medical Physicist in the field of expertise (i.e. Nuclear Medicine, Radiology or Radiation Oncology). I recently came across an advert for Medical Physicists in Australia. That made me thinking there may be another solution as how to recognise Medical Physics profession in Australia without the consideration of being AHPRA registered nor being part of a national body to manage the Medical Physicists’ registration. I strongly suggest to ARPANSA to focus on the medical physicist definition of IAEA and to use the examples above to promote as how to manage the professional definition for medical physicists and their roles and responsibilities based on the IAEA definitions given in the reference GSR Part 3. This recommendation means that ARPANSA must curtail to recommend when it allows other individuals to practice in the capacity of medical physicists without the appropriate qualifications as stated by IAEA and above. Dosimetry calculations made by medical physicists in all areas of expertise does not include the activities that other technologists/radiation scientists/radiographers/medical radiation practitioners do, though some part of the dosimetry could be performed by other professionals the calculations are entirely different. | Noted. |
| 382 | ADIA | General | Referral | ADIA has one particular concern. Several sections within the draft Code could be interpreted as requiring radiologist involvement in justification and approval of medical exposure well beyond what is practical in a busy practice setting, or what is necessary to protect patients. For example: Medical exposure must be justified by communication between the radiologist and the referrer “as appropriate”. In most cases appropriate communication is satisfied by the request form. If this section is interpreted as requiring additional communication, the radiologist workload will increase substantially, with minimal safety benefits for patients. | A footnote has be added to indicate that: "A written request with adequate clinical information on which to base a justification will usually meet the requirement for communication. However, contact information for the referrer must be provided to facilitate further communication, should it be required." |
| 20 a | Penny Hill - ACT | General | Formatting | A number of formatting comments in Draft document. Which/that, punctuation for sub-clauses, and/or in sub clauses, bolding on first use | The writing style of the document is consistent with that in the Planned Exposure Code (RPS C-1) |
| 145 a | Australian Society of Medical Imaging and Radiation Therapy (ASMIRT) | Readers Guide | Readers Guide | Readers guide: Radiation Protection in Medical Exposure | This was a document created for the public consultation process to help respondents understand the Code. It is not intended for separate publication. |
| 145 c | Australian Society of Medical Imaging and Radiation Therapy (ASMIRT) | Readers Guide 23-25 | Readers Guide | Line 23-25: Dose assessments are not only performed by medical physicists. Include dose assessments by medical radiation practitioners. |  |
| 145 d | Australian Society of Medical Imaging and Radiation Therapy (ASMIRT) | Readers Guide 39-41 | Readers Guide | Line 39-41: The fact that all involved have a collective responsibility for justification and optimisation should come first, before the individual responsibilities. |  |
| 145 e | Australian Society of Medical Imaging and Radiation Therapy (ASMIRT) | Readers Guide 40 | Readers Guide | Line 40: correct the term technologist. |  |
| 145 f | Australian Society of Medical Imaging and Radiation Therapy (ASMIRT) | Readers Guide 42-60 | Readers Guide | Line 42-60: Why does the new code use the term medical physicist instead of the term qualified expert? If the definition is the same as RPS14, why is the term qualified expert not retained? A qualified expert is a person who: (a) is qualified in the application of the physics of therapeutic or diagnostic uses of ionizing radiation; and (b) has been recognised by the relevant regulatory authority as being able to perform the dosimetric calculations, radiation measurements and monitoring relevant to the person’s area of expertise[14] Both of these are clearly within the remit of medical radiation practitioners and the fact that the role of Radiation Safety Officer is undertaken by medical radiation practitioners attests to this. |  |
| 146 a | Australian Society of Medical Imaging and Radiation Therapy (ASMIRT) | Readers Guide 48 | Readers Guide | Line 48: Every state has slightly different rules from their regulators and this can cause confusion. It would be helpful if the ARPANSA document incorporated and made sense of each state requirement. |  |
| 146 b | Australian Society of Medical Imaging and Radiation Therapy (ASMIRT) | Readers Guide 66-70 | Readers Guide | Line 66-70: In practice, the majority of requests for diagnostic imaging would not be sighted by the radiologist before imaging takes place. Nor would it be practical for this to occur. Medical radiation practitioners as educated professionals are determining the justification for proceeding, or not. Departmental guidelines are in place to notify the radiologist if there is any query arising from a request before proceeding. |  |
| 145 b | Australian Society of Medical Imaging and Radiation Therapy (ASMIRT) | Readers Guide 8-9 | Readers Guide | Line 8-9: Whilst ASMIRT applauds ARPANSA’s desire to align with world’s best practice; the Code for Australia should reflect the context of the delivery of medical radiations in Australia. This includes the significant differences in education and training, particularly with respect to that of medical radiation practitioners. |  |
| 146 c | Australian Society of Medical Imaging and Radiation Therapy (ASMIRT) | Readers Guide 92 | Readers Guide | Line 92: ASMIRT welcomes the periodic independent verification of calibrations of external beam radiation therapy units by the Australian Clinical Dosimetry Service, and the requirement for periodic internal review by the medical radiation team of systems, processes and procedures. |  |
| 87 | Anonymous | Safety Guide | Safety Guide | As a side issue, Table 10, Annex d, RPS 14.2, requires review. Lu-177 should be included and possibly Ac-225 and daughters. Use of these in therapeutic nuclear medicine is increasing rapidly. | Noted. |