



# Resolution of comments from stakeholder submissions on Standard for Radiation Safety and Performance Testing of Diagnostic Imaging Apparatus. Radiation Protection Series S-2

Consultation period: 9th November 2021 - 31st January 2022

The Radiation Health Committee (RHC) is formed under the *Australian Radiation Protection and Nuclear Safety Act 1998*, to advise the CEO of the Australian Radiation Protection and Nuclear Safety Agency upon request. A Working Group was formed under the RHC to review the radiation apparatus testing requirements across Australia and, in a move towards national consistency, to prepare a standards document to represent a national position, which jurisdictions could adopt, as a whole or in part, or move towards over time as and when their jurisdictional requirements were amended. The Working Group included members from most jurisdictions including Queensland, Tasmania, Victoria, South Australia, Western Australia, and the Australian Capital Territory.

Following endorsement in November 2021 by the RHC for the document to go out for consultation, a consultation process was facilitated by ARPANSA between 9th November 2021 and 31st January 2022. During and following the consultation process comments on the document were submitted by individuals and on behalf of organisations, including Medical Physicists, engineers, radiation protection regulators, medical imaging providers, and by representatives from professional bodies including RANZCR MQAP, ACPSEM and ASMIRT.

Comments were grouped into sections according to the aspect they related to for Parts A, B and C, or the apparatus type and the particular test for Appendices 1 - 4. This was to allow all comments on a particular aspect of the document to be considered at once, and to identify any common themes.



# **Australian Government**

# Australian Radiation Protection and Nuclear Safety Agency



|   | and Nuclear Safety Agency |  |   |  |  |
|---|---------------------------|--|---|--|--|
|   |                           |  | Comments by reviewers   | Resolution   |  |
| # | Section                   | Subject  | Comments  | Response   |  |
| 1 | Parts A, B and C          | Consistency of terminology   | There was variation in the terminology used across different sections of the document, which needed to be identified and addressed  | The document was reviewed and updated with the aim of ensuring consistency of terminology.   |  |
| 2 | Parts A, B and C          | Wording 'safety tests'   | Using the term 'safety tests' rather than 'compliance tests'. Including 'and performance' in the term used for the tests.   | It was agreed to incorporate this change and to include 'and performance' in the wording, as not all of the tests were strictly related to safety.   |  |
| 3 | Parts A, B and C          | Distinction between compliance tester and person issuing the Certificate of Compliance and the inspection report | Clarification of terminology and the inclusion of a two-<br>tiered system of compliance tester and person<br>authorised to issue Certificates of Compliance.  | It was agreed that a two-tiered approach would allow for a greater number of compliance testers, whilst the oversight of a person authorised to issue Certificates of Compliance would ensure quality of testing and data in the reports produced. |  |
| 4 | Parts A, B and C          | Actions following identification of a critical failure   | Comments indicated that greater flexibility was required in the event of a critical failure being identified, to permit the continued operation of the apparatus pending service/repair, provided the circumstances of the critical failure could be avoided. | It was agreed to have a risk-based approach incorporating some flexibility and, where appropriate, a timeframe agreed in consultation with the regulator on a case-by-case basis.  |  |
| 5 | Parts A, B and C          | Critical failures  | Requirement to inform the regulator regarding critical failures.  | The requirements were reviewed and updated in relation to actions following identification of critical failures.   |  |
| 6 | Parts A, B and C          | Certificate of Compliance  | Clarification regarding responsibility for the inspection report and for issuing the Certificate of Compliance.   | It was agreed that the Certificate of Compliance and the compliance inspection report should be issued only by a person authorised to issue Certificates of Compliance, but that the testing can   |  |

|    |                  |  | Comments by reviewers  | Resolution  |
|----|------------------|--|--|---|
| #  | Section          | Subject  | Comments   | Response  |
|    |                  |  |  | be carried out by a suitably licensed compliance tester.  |
| 7  | Parts A, B and C | Notice of non-compliance                             | Actions following the identification of non-compliance with the standards.                                   | It was agreed that a 'Notice of non-compliance' would provide the source owner with written notification of the matters which need to be addressed.   |
| 8  | Parts A, B and C | Timing of testing                                    | Difficulty with being unable to use apparatus following testing if one or more non-compliance is identified. | It was agreed that the allowance of 30 days for rectification of a non-compliance provided time for any issues identified to be addressed. Further time could be permitted by the relevant regulatory authority on a case-by-case basis upon application. Any critical failures would need to be addressed more urgently and in accordance with the regulator's requirements. |
| 9  | Parts A, B and C | Frequency of testing                                 | Various suggestions for alternative testing frequencies were submitted.                                      | It was agreed to retain the frequencies on the document, as there was no consensus for any specific change. However, flexibility has been introduced with the Note.   |
| 10 | Parts A, B and C | Time allowed for addressing of non-compliances       | Concern around availability of engineers, replacement parts and compliance testers for repeat testing.       | It was agreed that the updated Sections 12 and 13 provide flexibility and that the source owner could approach the regulator for special consideration on a case-by-case basis if this was not sufficient.  |
| 11 | Parts A, B and C | Requirements for dental apparatus not being included | Suggestions that requirements for dental apparatus be included.  | It was agreed that the requirements for dental apparatus (intraoral, OPG and CBCT) would be added to the document at a later stage.   |
| 12 | Parts A, B and C | Labels   | Suggestion to include detector details   | It was decided not to include detector details as a requirement.  |

|    |  |   | Comments by reviewers  | Resolution   |
|----|--|---|--|--|
| #  | Section  | Subject   | Comments   | Response   |
| 13 | Computed<br>Tomography<br>scanners<br>(Appendix 1) | Radiation therapy simulation<br>CTs and SPECT/CTs or PET/CTs        | Query whether CT testing includes therapy simulation CTs and the CT aspects of PET/CT and SPECT/CT, and the patient positioning CBCT included with radiation therapy equipment.  | It was agreed that SPECT/CT and PET/CT are now included under 'diagnostic nuclear medicine imaging'. There has been clarification of requirements in relation to therapy planning (simulation) CTs. Patient positioning CBCT associated with LINACs would not be included. |
| 14 | Computed Tomography scanners (Appendix 1)          | Exclusions  | Suggest a more general term is used such as '3D volumetric interoperative fluoroscopic units', with 'O-arm' as an example.   | It was agreed to update the wording, and in the fluoroscopy section as well.   |
| 15 | Computed Tomography scanners (Appendix 1)          | Markings including tube details                                     | Some information may not be readily visible.   | It was agreed that if the required labelling is missing or not easily visible one possible solution is to add a label at a visible location on the gantry.   |
| 16 | Computed<br>Tomography<br>scanners<br>(Appendix 1) | Baseline values – establishing,<br>and justification of any changes | Potential difficulty with obtaining previously established baseline values and with justifying any changes.  Suggestion that the report includes measured data, test parameters and equipment, along with clinical justification for any change in the baseline. | It was agreed that the previously established baseline values must be made available to the compliance tester, or person approved to issue a Certificate of Compliance, to enable comparison. Additional wording included to require test parameters.                      |
| 17 | Computed Tomography scanners (Appendix 1)          | Baseline values – establishing,<br>and justification of any changes | Including the compliance tester in discussions justifying baseline changes.  | It was agreed that this had been resolved by other changes to the wording.   |
| 18 | Computed<br>Tomography                             | Radiation warning signage   | Required wording and minimum size of warning sign  | It was agreed that black on a yellow background and the trefoil symbol with appropriate wording is   |

|    |  |                                | Comments by reviewers  | Resolution  |
|----|--|--------------------------------|--|---|
| #  | Section  | Subject                        | Comments   | Response  |
|    | scanners<br>(Appendix 1)                           |                                |  | sufficient and there is no minimum label size as this would depend on the location.   |
| 19 | Computed Tomography scanners (Appendix 1)          | Illuminated warning signage    | Query the suitability of requirement for illumination during 'prep mode'.  | It was agreed to change warning light to 'duration of the exposure'.  |
| 20 | Computed Tomography scanners (Appendix 1)          | Termination of exposure        | 'Means must be provided to terminate the exposure', but this must also be functioning  | It was agreed that 'means must be provided to terminate' includes the requirement that it must also be working.   |
| 21 | Computed Tomography scanners (Appendix 1)          | Visible indicators of exposure | Request to review use of the terms 'visible indicator' and 'beam on'.  | It was agreed to update the heading to make the difference clearer.   |
| 22 | Computed Tomography scanners (Appendix 1)          | Indicators of exposure factors | Suggest these are included as a requirement on the control panel.  | It was agreed to add requirements at 5.3 for indicators of exposure parameters on the control panel.  |
| 23 | Computed<br>Tomography<br>scanners<br>(Appendix 1) | Light localisation             | Comments in relation to the lights/lasers and their coincidence with each other and the scan plane, and the mechanical accuracy of couch movement.  Acknowledgement that external plane lights are not available on some models. | It was agreed to add wording from the VIC standard and AS/NZS.  It was agreed to adjust the wording to include 'if external plane lights are available'.  It was agreed to include the RP162 requirement of 5mm for diagnostic imaging and to restrict the more stringent critical failure level to radiation therapy planning apparatus. |

|    |  |                            | Comments by reviewers  | Resolution   |
|----|--|----------------------------|--|--|
| #  | Section  | Subject                    | Comments   | Response   |
| 24 | Computed Tomography scanners (Appendix 1)          | Light localisation         | Critical failure values not suitable/not required for all situations.  | It was agreed that this comment had been addressed by only including a critical failure level for therapy planning CT. |
| 25 | Computed Tomography scanners (Appendix 1)          | Light localisation         | Query wording  | It was agreed that the Note clarifies the meaning and to retain this wording.  |
| 26 | Computed Tomography scanners (Appendix 1)          | Preview image localisation | Accuracy is essential as it is the main method for slice selection.  | It was agreed that this is included.   |
| 27 | Computed Tomography scanners (Appendix 1)          | Image quality              | Suggest that evaluation of noise and mean CT number is not needed for every slice (image) as there may be many slices. | It was agreed to remove the requirement for evaluation of every slice.   |
| 28 | Computed<br>Tomography<br>scanners<br>(Appendix 1) | Noise                      | Suggest comparison with AS/NZS value.  | It was agreed to include 0.2HU as included in the VIC standard which is ultimately from the Australian Standard.       |
| 29 | Computed<br>Tomography<br>scanners<br>(Appendix 1) | Noise                      | Comparison with baseline vs requiring absolute values.   | It was agreed that requiring the manufacturer-<br>specified tolerances could represent the absolute<br>measurement.    |
| 30 | Computed<br>Tomography                             | Mean CT number             | Critical failure level - suggest using RP162 value of 10HU.  | It was agreed to include the suggestion.   |

|    |   | Comments by reviewers         |   | Resolution   |
|----|---|-------------------------------|---|--|
| #  | Section                                   | Subject                       | Comments  | Response   |
|    | scanners<br>(Appendix 1)                  |                               |   |  |
| 31 | Computed Tomography scanners (Appendix 1) | Uniformity                    | Critical failure levels, depending on phantom diameter.   | It was agreed that the critical failure levels are now as suggested.                       |
| 32 | Computed Tomography scanners (Appendix 1) | Reconstructed slice thickness | Suggest this is restricted to all reconstructed slice thicknesses used clinically.                        | It was agreed to include this change, and to a change in the heading.                      |
| 33 | Computed Tomography scanners (Appendix 1) | Reconstructed slice thickness | Wording is unclear.   | It was agreed to add words to clarify.   |
| 34 | Computed Tomography scanners (Appendix 1) | Reconstructed slice thickness | Suggest removing this test for multi-slice scanners as it is not determined by the collimator jaws.       | It was agreed to retain the existing wording.  |
| 35 | Computed Tomography scanners (Appendix 1) | Low contrast resolution       | Query requirement for low contrast resolution test.   | It was agreed to require this test only for equipment used for radiation therapy planning. |
| 36 | Computed Tomography scanners (Appendix 1) | Low contrast resolution       | Query whether spatial and low contrast resolution testing are really needed as they are unlikely to fail. | It was agreed that this test is only required for Radiation Therapy planning apparatus.    |

|    |  |   | Comments by reviewers   | Resolution  |
|----|--|---|---|---|
| #  | Section  | Subject                                   | Comments  | Response  |
| 37 | Computed Tomography scanners (Appendix 1)          | Spatial resolution                        | Spatial resolution is unlikely to fail - reconsider whether it is really needed.                                    | It was agreed to remove the test as suggested.  |
| 38 | Computed Tomography scanners (Appendix 1)          | CTDI in air                               | Query the number of nominal beam collimations to be tested  | It was agreed to retain the requirement for testing 5 beam collimations.  |
| 39 | Computed<br>Tomography<br>scanners<br>(Appendix 1) | CTDI in air                               | Suggested review of the wording compared with IEC 61223-3-5:2019.   | It was agreed to add wording in the critical failure information which included deviation from the baseline values.   |
| 40 | Computed Tomography scanners (Appendix 1)          | CTDI in air                               | Critical failure value  | It was agreed to adjust the wording, in line with other tests, to require being within manufacturer tolerances, where provided, AND meeting the other requirements indicated. |
| 41 | Computed Tomography scanners (Appendix 1)          | Volume CT Dose Index<br>(CTDI vol)        | Retaining CTDI vol tests, as this is the relevant dosimetric parameter and is specified on all types of CT scanners | It was agreed that this is now included in 8.2  |
| 42 | Computed Tomography scanners (Appendix 1)          | CTDI vol and Dose Length<br>Product (DLP) | Suggestion that the requirement for this to be 'available to the operator and recorded with CT images' be removed.  | It was agreed to keep this as it is available so it should be recorded.   |
| 43 | Computed Tomography scanners (Appendix 1)          | CTDI vol                                  | Include requirements for typical head and body scans, and DLP.  | It was agreed to incorporate this suggestion and the wording was changed to include comparison with the displayed values.   |

|    |  | Comments by reviewers             |   | Resolution   |
|----|--|-----------------------------------|---|--|
| #  | Section  | Subject                           | Comments  | Response   |
| 44 | Computed Tomography scanners (Appendix 1)          | Manufacturer specified tolerances | Query if these were unavailable.  | It was agreed that the manufacturer could be requested to provide them, and that the IAEA includes this requirement.   |
| 45 | Computed<br>Tomography<br>scanners<br>(Appendix 1) | Axial mode                        | Query availability of axial mode.   | It was agreed that axial mode needs to be available as it is needed for many of the tests.   |
| 46 | Computed<br>Tomography<br>scanners<br>(Appendix 1) | Other                             | Suggestions for additional tests  | It was agreed that HVL and kVp accuracy or reproducibility should be in the acceptance testing and that any issues with them would become evident in image quality tests which could then be investigated further by the service engineer. |
|    |  |                                   |   | It was agreed that before adding further tests a benefit would need to be demonstrated.  |
| 47 | Mammography apparatus (Appendix 2)                 | Option 1 - Accreditation program  | Suggest changing from 'and' to 'or' for BreastScreen NAS and RANZCR.                                      | It was agreed to change the wording to 'or' as suggested.  |
| 48 | Mammography apparatus (Appendix 2)                 | Option 1 – Accreditation program  | Suggest updating the title of the RANZCR Guidelines.  | It was agreed to change the wording as suggested.  |
| 49 | Mammography apparatus (Appendix 2)                 | Option 2                          | Suggest updating the title of the ACPSEM Position Paper.  | It was agreed to adjust the wording as suggested.  |
| 50 | Mammography apparatus (Appendix 2)                 | Critical failure levels           | Critical failure levels had not been included in the document and it was felt that they should have been. | It was agreed to include critical failure levels for mammography apparatus.  |

|    |                                    |   | Comments by reviewers  | Resolution   |
|----|------------------------------------|---|--|--|
| #  | Section                            | Subject   | Comments   | Response   |
| 51 | Mammography apparatus (Appendix 2) | Radiation warning signage   | Softening of wording required on the radiation warning signage and removal of the requirement for an illuminated warning sign. | It was agreed to incorporate the suggestions and to remove the requirement for an illuminated warning sign.                        |
| 52 | Mammography apparatus (Appendix 2) | X-ray beam collimation and alignment                                | The image receptor is not fully irradiated in magnification mode.  | It was agreed to add a note that 5.1(a) does not apply to Mag mode.  |
| 53 | Mammography apparatus (Appendix 2) | kVp Accuracy and<br>Reproducibility                                 | Suggest testing all target/filter combinations which have a different kV calibration.  | The wording for 6.2 was adjusted to include some wording from 6.1 to clarify the situation.  |
| 54 | Mammography apparatus (Appendix 2) | Beam quality  | Suggest these requirements are removed as RANZCR has removed them.   | It was agreed that a tolerance is still required and that more evidence would be needed before changing from this accepted method. |
| 55 | Mammography apparatus (Appendix 2) | AEC performance –<br>Reproducibility                                | Suggest changing absorbed dose to Mean Pixel Value (MPV)   | It was agreed to change absorbed dose to mean pixel value as suggested, which is also in line with QLD's requirements.             |
| 56 | Mammography apparatus (Appendix 2) | Thickness compensation and SDNR System Performance (CR and DR only) | 2mm Al should be 0.2mm Al.   | It was agreed that this was a typographical error and the value 2mm was changed to 0.2mm Al.                                       |
| 57 | Mammography apparatus (Appendix 2) | AEC Thickness Compensation (Tomosynthesis mode only)                | The wording of this test is unclear.   | It was agreed to add wording which clarified the intention of the test.  |
| 58 | Mammography apparatus (Appendix 2) | Monitor testing   | Update AAPM TG18 to TG270.   | It was agreed to retain TG18 until such time as RANZCR adopts an alternative.  |

|    |  |   | Comments by reviewers  | Resolution  |
|----|--|---|--|---|
| #  | Section                                  | Subject   | Comments   | Response  |
| 59 | Mammography apparatus (Appendix 2)       | System resolution                               | Suggest including MTF test tool. Query requirement for 4.5cm as most testers would have 4cm PMMA or 4.2cm ACR phantom. | It was agreed to change this to 4cm as suggested, and to include the MTF tool which is indicated in the ACPSEM position paper.  |
| 60 | Mammography apparatus (Appendix 2)       | Artefact evaluation                             | Suggest including 'any clinically significant artefacts' and listing a-f as examples.                                  | It was agreed to include a – f as suggestions and to include additional wording in keeping with this comment.   |
| 61 | Mammography apparatus (Appendix 2)       | Distance calliper accuracy                      | Suggest additional calliper testing requirements.  | It was agreed to include wording to address these suggestions.  |
| 62 | Mammography<br>apparatus<br>(Appendix 2) | Image receptor ghosting                         | Suggest retaining consistency with RANZCR in the way the equation is written, i.e.   (MPV2-MPV1)/SD2                   | It was agreed to include additional wording in keeping with RANZCR. Mathematically the absolute value will be the same and MPV1-MPV2 is as indicated in the ACPSEM Position Paper, so this was retained.  |
| 63 | Mammography apparatus (Appendix 2)       | Exposure indicator calibration and image fading | Suggest including image fading.  | It was agreed to include image fading as it is included in the ACPSEM Position Paper.   |
| 64 | Mammography<br>apparatus<br>(Appendix 2) | Mean glandular dose (MGD)                       | Suggest clarification of the modes and review of the values.   | It was agreed to keep the values as indicated, based on a combination of the requirements of the ACPSEM Position Paper and NZ Ministry of Health requirements, which are not exactly the same as each other. WG included requirements for contact and tomosynthesis modes as suggested. |
| 65 | Mammography apparatus (Appendix 2)       | Mechanical stability                            | Suggest including a general mechanical inspection to check for vibration of CR units and any wobble after moving.      | It was agreed to retain the existing wording as it already requires that the assembly remain stable after positioning.  |

|    |  | Comments by reviewers                                  |  | Resolution  |
|----|--|--|--|---|
| #  | Section                                  | Subject  | Comments   | Response  |
| 66 | Mammography<br>apparatus<br>(Appendix 2) | Fogging  | Consider including assessment of dark noise and fogging for CR systems.  | It was agreed that fogging due to insufficient shielding at the storage location of the plates would need to be assessed over a significant period of time which would not be available to the compliance tester, and therefore this should be part of QA testing rather than compliance testing. |
| 67 | Mammography apparatus (Appendix 2)       | Other  | Suggestions for other tests  | It was agreed that the suggestions could form part of the weekly QA rather than being included in annual compliance testing.  |
| 68 | Fluoroscopy<br>apparatus<br>(Appendix 3) | Markings   | Relative position of anode and cathode may be difficult to determine in an O-arm   | It was agreed to remove this requirement for fluoroscopy as the focal spot is not readily identifiable externally on all instruments. The tester will need to make an estimate of the focal spot position in order to carry out tests where a distance from the focal spot needs to be measured.  |
| 69 | Fluoroscopy<br>apparatus<br>(Appendix 3) | Radiation warning signage                              | Suggest that there should be a warning sign at entry doors when a mobile C-arm is in use.  | It was agreed to include the requirement for warning signage for rooms where mobile units are in use.   |
| 70 | Fluoroscopy<br>apparatus<br>(Appendix 3) | Indicators of operation                                | Include pulse rate   | It was agreed to include pulse rate as well.  |
| 71 | Fluoroscopy<br>apparatus<br>(Appendix 3) | Indicators of operation                                | Suggest including a requirement that if the system has AEC spectral beam filtration this must be displayed.  | It was agreed to adjust the wording to address this and another similar comment.  |
| 72 | Fluoroscopy<br>apparatus<br>(Appendix 3) | Exposure switch - Prevention from accidental operation | Shrouding not defined – query whether a raised edge on the foot switch could suffice as this would prevent foot getting caught in the foot switch. | It was agreed that the existing wording is sufficient as it includes shrouding as one possible way of achieving this.   |

|    |  |   | Comments by reviewers   | Resolution   |
|----|--|---|---|--|
| #  | Section                                  | Subject                                     | Comments  | Response   |
| 73 | Fluoroscopy<br>apparatus<br>(Appendix 3) | Radiographic exposure                       | Query wording regarding initiation of another exposure  | It was agreed to add wording to clarify this.  |
| 74 | Fluoroscopy<br>apparatus<br>(Appendix 3) | Protection of the operator at the tableside | Some systems may struggle to meet this requirement.   | It was agreed that these requirements are for fixed fluoroscopy installations and if they are unable to meet the protection of those in the room the facility may need to upgrade those protections. |
| 75 | Fluoroscopy<br>apparatus<br>(Appendix 3) | Stability of the X-ray tube assembly        | Pass criteria ill defined. It is commonly required to move over table tubes during exposure, as long as there is matched receiver movement. | It was agreed to include some additional wording to cover the possibility of intended movement.  |
| 76 | Fluoroscopy<br>apparatus<br>(Appendix 3) | Stability of mobile apparatus               | 13.2 seems redundant given the requirements of 13.1   | It was agreed that these two requirements cover different aspects and added the example of lockable wheels to 13.1 to clarify this. 13.2 relates to the lockable C-arm position.                     |
| 77 | Fluoroscopy<br>apparatus<br>(Appendix 3) | kVp accuracy                                | Criteria are tighter than the IEC.  | It was agreed to leave the requirements as they are.   |
| 78 | Fluoroscopy<br>apparatus<br>(Appendix 3) | kVp accuracy                                | kVp should be accurate for automated systems as well as manually selectable.  | It was agreed to include automatically selected kV within the wording, and to clarify the wording with respect to the measured value compared with the indicated value.                              |
| 79 | Fluoroscopy<br>apparatus<br>(Appendix 3) | Radiographic timer accuracy                 | Query requirements – 10% is easily achievable. Wording should indicate that it applies for manually selectable systems.                     | It was agreed to keep the requirement, as it is consistent with the VIC, QLD and SA requirements. Wording was adjusted to clarify that it refers to radiographic exposures.                          |

|    |  |  | Comments by reviewers  | Resolution  |
|----|--|--|--|---|
| #  | Section                                  | Subject                                      | Comments   | Response  |
| 80 | Fluoroscopy<br>apparatus<br>(Appendix 3) | Protection of others in the room             | The 2m rule does not guarantee an acceptable dose rate for assistants  | It was agreed that the PPE is not part of the equipment so it should not be an equipment requirement. Availability of lead aprons is an administrative control and the tester or other user should request a lead apron before operating the equipment. |
| 81 | Fluoroscopy<br>apparatus<br>(Appendix 3) | Fluoroscopy radiation output reproducibility | Some systems don't have manual adjustment – suggest including an indication of whether 'around 80kVp' would be sufficient.   | It was agreed to change the wording to 'approximately 80kVp'.   |
| 82 | Fluoroscopy<br>apparatus<br>(Appendix 3) | Accuracy of output air kerma area product    | Suggest improving the guidance   | It was agreed to include more information in the guidance notes, in line with the suggestions in the comment.   |
| 83 | Fluoroscopy<br>apparatus<br>(Appendix 3) | Accuracy of output air kerma area product    | KAP should ideally be within 10%   | It was agreed to keep the existing values as they are in line with EC RP162 and the NZ requirements.  |
| 84 | Fluoroscopy<br>apparatus<br>(Appendix 3) | Audible signal at pre-set time               | Wording queried regarding automatic termination  | It was agreed to update the wording in line with the suggestion.  |
| 85 | Fluoroscopy<br>apparatus<br>(Appendix 3) | Beam quality                                 | Unlikely to be a problem if the post-2015 limits are applied. Suggest using the post-2015 HVL requirements for all           | It was agreed to remove the pre-and post-2015 distinction and to apply the post-2015 requirements as suggested.   |
| 86 | Fluoroscopy<br>apparatus<br>(Appendix 3) | Beam quality                                 | Suggest including a formula to calculate HVL limits based on kVp for situations where only a non-standard kVp is selectable. | It was agreed that a tester may use interpolation between the HVL values specified to account for kVp values not included in the table.   |
| 87 | Fluoroscopy<br>apparatus<br>(Appendix 3) | Last image hold                              | Suggest this would be picked up in entry requirements.   | It was agreed to retain the current wording.  |

|    |  |                                | Comments by reviewers  | Resolution   |
|----|--|--------------------------------|--|--|
| #  | Section                                  | Subject                        | Comments   | Response   |
| 88 | Fluoroscopy<br>apparatus<br>(Appendix 3) | Focus to skin distance         | Query having three requirements  | It was agreed to add wording for special surgical applications, as QLD has.  |
| 89 | Fluoroscopy<br>apparatus<br>(Appendix 3) | Beam alignment and collimation | The example uses a CR cassette - query why a CR cassette is described rather than the integrated digital detector. | It was agreed that the wording was taken from NSW and to bold the text indicating that 'other means to measure the radiation field area may be substituted'.   |
| 90 | Fluoroscopy<br>apparatus<br>(Appendix 3) | Beam alignment and collimation | Query test methodology as it seems overly complicated and departs from IEC standard for entry criteria.            | It was agreed to retain the requirement as it is, and to review the situation once the document is in use.   |
| 91 | Fluoroscopy<br>apparatus                 | Beam alignment and collimation | Properly aligned is poorly defined   | It was agreed to retain this requirement, as it is taken from NSW requirements.  |
|    | (Appendix 3)                             |                                |  | It covers the positive locking into position of the tube and image receptor in relation to each other if they are independently adjustable.  |
|    |  |                                |  | The requirement for the primary beam to be completely intercepted by the image receptor is covered by test 23.3.   |
| 92 | Fluoroscopy<br>apparatus<br>(Appendix 3) | Beam centred                   | Query tolerance  | It was agreed that this is a qualitative test and a tolerance value is not included.   |
| 93 | Fluoroscopy<br>apparatus<br>(Appendix 3) | Beam-limiting operation        | 23.4 seems redundant given the requirements of 23.1 and 23.3   | It was agreed that this is not the same as 23.1 and 23.3, and can be tested by selecting a smaller field size then trying to adjust the collimation to have the X-ray beam falling outside of that size.  It was agreed that current the wording would |
|    |  |                                |  | remain.  |

|    |  | Comments by reviewers                                      |  | Resolution  |
|----|--|--|--|---|
| #  | Section                                  | Subject  | Comments   | Response  |
|    |  |  |  | The wording for this section was taken from the NSW requirements in full.   |
| 94 | Fluoroscopy<br>apparatus<br>(Appendix 3) | Maximum ratio of radiation field area to imaged field area | Queried the wording  | It was agreed that the suggestion related to the use of the symbol ≤ rather than words, so this was updated accordingly.  |
| 95 | Fluoroscopy<br>apparatus                 | Beam collimation   | Queried wording of this requirement  | It was agreed that this was taken from NSW requirements in full and should be retained as is.   |
|    | (Appendix 3)                             |  |  | It is interpreted to mean that it must be possible to collimate down from the maximum field size.   |
| 96 | Fluoroscopy<br>apparatus<br>(Appendix 3) | Nominal field size   | Query the necessity of this test   | It was agreed to retain this test and to review the situation once the standard is being used in practice.  |
| 97 | Fluoroscopy<br>apparatus<br>(Appendix 3) | Exposure limit during image acquisition                    | Query 'cardiac mode' not being specifically indicated.   | It was agreed to include the '/Use' in the column heading, to allow for if there is not a specific mode indicated for cardiac use.  |
| 98 | Fluoroscopy<br>apparatus<br>(Appendix 3) | Exposure limit during image acquisition                    | Concern regarding the introduction of an exposure limit that may have undesired consequences on required clinical image quality. | It was agreed to retain this requirement as image acquisition has the potential to deliver very high doses to the patient.  |
|    |  |  |  | The specific value could be reviewed once the document is being used.   |
| 99 | Fluoroscopy<br>apparatus<br>(Appendix 3) | Exposure limit during image acquisition                    | Comments received following trialling of the test, requesting further information on suitable test conditions.                   | It was agreed to refer the test to the relevant ACPSEM Working Group for advice regarding suitable test conditions and to remove the test from the standards document in the meanwhile. |

|     |  |   | Comments by reviewers  | Resolution   |
|-----|--|---|--|--|
| #   | Section                                  | Subject   | Comments   | Response   |
| 100 | Fluoroscopy<br>apparatus<br>(Appendix 3) | Entrance air kerma rate at surface of image receptor during fluoroscopy | Comparison drawn with test 25 – exposure limit during image acquisition  | It was agreed that this test is done at typical settings (70-80kVp) rather than at maximum settings, so it is a different test and should remain. Also the tests in 25 and 27 are in two different modes (acquisition and fluoroscopic). |
| 101 | Fluoroscopy<br>apparatus<br>(Appendix 3) | Entrance air kerma rate at surface of image receptor during fluoroscopy | Suggest including a thickness of Cu or PMMA rather than 70-80kV.   | It was agreed that Copper or Aluminium is used as an attenuation material in order to achieve the 70kV-80kV. However, it was agreed that some systems may require the use of a contrast phantom instead.                                 |
| 102 | Fluoroscopy<br>apparatus<br>(Appendix 3) | Entrance air kerma rate at surface of image receptor during fluoroscopy | Suggest specifying measurements to be taken using the most clinically used programs and to comply with manufacturer's specifications or be within 10% of baseline. | It was agreed to retain the actual values for this test.   |
| 103 | Fluoroscopy<br>apparatus<br>(Appendix 3) | Entrance air kerma rate at surface of image receptor during fluoroscopy | Query field sizes included as cardiac units can go down to 9cm.  | It was agreed that 9cm field sizes are outside the scope of the document and are not tested.   |
| 104 | Fluoroscopy<br>apparatus<br>(Appendix 3) | Incident air kerma rate at image receptor during DSA                    | Comparison drawn with IEC 203.5.2.4.5.101  | It was agreed to leave this requirement as it is.  |
| 105 | Fluoroscopy<br>apparatus<br>(Appendix 3) | Incident air kerma rate at image receptor during DSA                    | Suggestions regarding critical failure levels  | It was agreed to leave this requirement as it is.  |
| 106 | Fluoroscopy<br>apparatus<br>(Appendix 3) | Incident air kerma rate at image receptor during DSA                    | Query test conditions  | It was agreed to add 2.5mm Cu in-beam to represent a patient-equivalent which would drive the voltage to 90kV in most cases.   |

|     |  |  | Comments by reviewers   | Resolution  |
|-----|--|--|---|---|
| #   | Section                                  | Subject  | Comments  | Response  |
| 107 | Fluoroscopy<br>apparatus<br>(Appendix 3) | Incident air kerma rate at image receptor during DSA                                 | Comments received following trialling of the test, requesting further information on suitable test conditions.  | It was agreed to refer the test to the relevant ACPSEM Working Group for advice regarding suitable test conditions and to remove the test from the standards document in the meanwhile.                                   |
| 108 | Fluoroscopy<br>apparatus<br>(Appendix 3) | Incident air kerma rate at image receptor during cinefluorography                    | Comparison drawn with IEC 203.5.2.4.5.101   | It was agreed to leave this requirement as it is.   |
| 109 | Fluoroscopy<br>apparatus<br>(Appendix 3) | Incident air kerma rate at image receptor during cinefluorography (acquisition mode) | Query test conditions   | It was agreed to add 2.5mm Cu in-beam to represent a patient-equivalent which would drive the voltage to 90kV in most cases.  |
| 110 | Fluoroscopy<br>apparatus<br>(Appendix 3) | Incident air kerma rate at image receptor during cinefluorography (acquisition mode) | Comments received following trialling of the test, requesting further information on suitable test conditions.  | It was agreed to refer the test to the relevant ACPSEM Working Group for advice regarding suitable test conditions and to remove the test from the standards document in the meanwhile.                                   |
| 111 | Fluoroscopy<br>apparatus<br>(Appendix 3) | High-contrast resolution of the live image   | Suggest inclusion of following manufacturer's specifications and suggest using the same wording as following test "placed directly onto centre of image receptor" | It was agreed that following the manufacturer specifications for the test object is mentioned in dot point 4 and therefore it was agreed to leave this requirement as it is.  Wording was adjusted as suggested regarding |
| 112 | Fluoroscopy<br>apparatus<br>(Appendix 3) | Low-contrast resolution and low-contrast threshold of the live image                 | Suggest requiring a constancy test using performance established at acceptance  | being placed onto the image receptor.  It was agreed to leave this requirement as it is.  |

|     |  | Comments by reviewers  |  | Resolution  |
|-----|--|--|--|---|
| #   | Section  | Subject  | Comments   | Response  |
| 113 | Fluoroscopy<br>apparatus<br>(Appendix 3)                 | Low-contrast resolution and low-contrast threshold of the live image | Query the term Westmead Phantom.   | Wording changed to Westmead test object.  |
| 114 | Fluoroscopy<br>apparatus<br>(Appendix 3)                 | Low-contrast resolution  | Suggest including a catch-all for 'any clinically significant artefacts or distortion' | It was agreed to include this wording.  |
| 115 | Fluoroscopy<br>apparatus<br>(Appendix 3)                 | Radiation leakage  | Should specify averaged over 100cm <sup>2</sup>  | It was agreed to include this wording.  |
| 116 | Plain<br>Radiographic<br>X-ray apparatus<br>(Appendix 4) | Opening section  | Review the scope.  | The opening section for this appendix was reviewed and it was agreed that it would remain unchanged.  |
| 117 | Plain<br>Radiographic<br>X-ray apparatus<br>(Appendix 4) | Accuracy of kilovoltage controls (kVp accuracy)                      | Should be assessed over the clinically used range                                      | It was agreed that this was an omission from the document and to include suitable wording.  |
| 118 | Plain<br>Radiographic<br>X-ray apparatus<br>(Appendix 4) | Accuracy of kilovoltage controls (kVp accuracy)                      | Query 6% used in another jurisdiction  | It was agreed to retain 5%.   |
| 119 | Plain<br>Radiographic<br>X-ray apparatus<br>(Appendix 4) | Timer accuracy   | 10% or one pulse for clinically used times   | It was agreed to remain consistent with the VIC,<br>QLD and SA requirements, which includes 'or one<br>pulse' for exposure times less than 0.1s |
| 120 | Plain<br>Radiographic                                    | Timer accuracy   | Critical failure values seem unacceptable  | It was agreed that the normal values indicated represent achievable levels (and are not as  |

|     |  | Comments by reviewers                        |  | Resolution   |
|-----|--|--|--|--|
| #   | Section  | Subject                                      | Comments   | Response   |
|     | X-ray apparatus<br>(Appendix 4)                          |  |  | stringent as the NZ and NSW requirements of 5%) and the critical failure levels of 20% and 30% were taken from EC RP162. It was agreed to retain the existing wording.   |
| 121 | Plain<br>Radiographic<br>X-ray apparatus<br>(Appendix 4) | Radiation output (air kerma) reproducibility | Three exposures may be sufficient to assess this rather than five exposures.                           | It was agreed that five exposures would better represent a number which could identify a variation outside of the requirements and is not excessive.  This is consistent with the requirement for five exposures in other parts of the document. |
| 122 | Plain<br>Radiographic<br>X-ray apparatus<br>(Appendix 4) | Radiation output (air kerma)<br>linearity    | Critical failure value seems unacceptable  | This value was compared with the requirements of other jurisdictions, including EC RP162 and QLD, and it was agreed to change this to 0.1  |
| 123 | Plain<br>Radiographic<br>X-ray apparatus<br>(Appendix 4) | Automatic exposure control (AEC)             | Include visual indicators of which chambers are selected   | It was agreed to add this requirement as suggested.  |
| 124 | Plain<br>Radiographic<br>X-ray apparatus<br>(Appendix 4) | Termination by AEC                           | Add the requirement that the delivered mAs must be visually displayed following termination by the AEC | It was agreed that if this is not included on equipment it would be onerous to retrofit.  Therefore the existing wording was retained.   |
| 125 | Plain<br>Radiographic<br>X-ray apparatus<br>(Appendix 4) | Automatic exposure control (AEC)             | Recommend including mean pixel value (MPV) as an alternative to exposure index (EI).                   | It was agreed to include MPV as a possible alternative as some jurisdictions give their requirements in terms of the MPV.  |

|     |  |                                  | Comments by reviewers  | Resolution   |
|-----|--|----------------------------------|--|--|
| #   | Section  | Subject                          | Comments   | Response   |
| 126 | Plain<br>Radiographic<br>X-ray apparatus<br>(Appendix 4) | Automatic exposure control (AEC) | Add the requirement that all chambers should be reproducible.  | It was agreed to adjust the wording to incorporate the suggestion.   |
| 127 | Plain<br>Radiographic<br>X-ray apparatus<br>(Appendix 4) | Minimum focus to skin distance   | Review the wording for suitability   | The section was reviewed and it was agreed that the wording should remain the same.  |
| 128 | Plain<br>Radiographic<br>X-ray apparatus<br>(Appendix 4) | Beam quality filtration          | Include that measurement should be with minimum filtration in the beam.  | It was agreed that 'Permanent filtration' implies minimum filtration is in the beam, and it was agreed that the existing wording would be retained.                  |
| 129 | Plain<br>Radiographic<br>X-ray apparatus<br>(Appendix 4) | Beam quality filtration          | Suggest removing the distinction between pre- and post-2015 requirements   | It was agreed to remove the pre-and post-2015 distinction and to apply the post-2015 requirements as suggested.  |
| 130 | Plain<br>Radiographic<br>X-ray apparatus<br>(Appendix 4) | Other                            | Suggestions of other tests which could be included   | It was agreed that some of the suggested tests may be desirable but to retain the current scope of the testing which had been included for the consultation process. |
| 131 | Plain<br>Radiographic<br>X-ray apparatus<br>(Appendix 4) | Other                            | Additional tests - Laser lights/bucky markings. Include assessment of laser lights and their coincidence with bucky markings, light crosshairs and image centre. | It was agreed that before adding further tests a benefit would need to be demonstrated.  |
| 132 | Glossary   | Missing terms                    | Seems to be missing a few terms  | It was agreed to add definitions for 'Preparation mode' and 'Responsible Person' but not 'Axial mode'. It was agreed to add wording partly from                      |

|     |            | Comments by reviewers |   | Resolution  |  |
|-----|------------|-----------------------|---|---|--|
| #   | Section    | Subject               | Comments  | Response  |  |
|     |            |                       |   | the Australian Standard and adjusted slightly to match the style of this document.  |  |
| 133 | References | Edit reference        | Update title for MQAP position paper                        | It was agreed incorporate to this suggestion.   |  |
| 134 | References | Edit reference        | Update title for RANZCR mammography QC guidelines           | It was agreed to incorporate this suggestion.   |  |
| 135 | References | Reference query       | AS/NZS may not be up to date with IEC                       | It was agreed to remove references to AS/NZS for each modality as suggested, as the AS/NZS may not be up to date with IEC documents.      |  |
| 136 | References | Additional references | Add reference to IEC 61223-3-5:2019                         | It was agreed to add the reference and include the full title.  |  |
| 137 | References | Additional references | Add more recent position papers which are under development | It was agreed that more recent references could be added when they become available and adjusted the wording below the table accordingly. |  |