



the peak body and leading voice
for sonographers

Thursday, 23 September 2021

Dr Lance Lawler
President
The Royal Australian and New Zealand College of Radiologists
Level 9, 51 Druitt Street
Sydney NSW 2000 Australia

Via email: fcr@ranzcr.edu.au

Dear Dr Lawler,

Thank you for the opportunity to review the *RANZCR Position Statement on the Regulation of Artificial Intelligence in Medicine* that will inform the regulation of AI in Australia and New Zealand.

The Australasian Sonographers Association (ASA) agrees that recent technological advances in the field of artificial intelligence (AI) and the possibility of the rapid dissemination of this technology throughout the Australian and New Zealand healthcare systems create a need to establish effective regulatory frameworks for intelligent medical software and that AI education within our professions will be essential.

The draft statement has been reviewed by an ASA panel of expert sonographers with knowledge of the application of AI in diagnostic imaging. This review supports the position statement. It also identified some areas on how the statement could be enhanced. This feedback, with line references, is attached.

On behalf of the ASA, I am pleased to confirm our support for this position statement and encourage adopting our recommended changes.

If you have any questions or require additional information supporting this feedback, please contact the ASA Policy Advisor, James Brooks-Dowsett, by phone at +61 406 998 429 or email to policy@sonographers.org.

Thank you again for your continued leadership in this area. We look forward to working with the College to support the increased utilisation of AI in medical diagnostic imaging in a way that improves patient care, supported by appropriate safeguards.

Yours sincerely,

Ian Schroen
President of the Board
The Australasian Sonographers Association

Attachment: ASA feedback on the RANZCR Position Statement on the Regulation of Artificial Intelligence in Medicine

The *RANZCR Position Statement on the Regulation of Artificial Intelligence in Medicine* has been reviewed by an ASA panel of expert sonographers with knowledge of the application of AI in diagnostic imaging.

The ASA's review supports the position statement and identifies opportunities for enhancement. This feedback, with line references, is below for consideration by the College.

Line reference/element	ASA comment/recommendation
Title of the statement	<p>Stating the 'Regulation of Artificial Intelligence in Medicine' could be misinterpreted that this document applies to all areas of medicine.</p> <p>We recommend reconsidering the title statement.</p>
Lines 132-134 (third bullet point)	<p>To be inclusive of all health professions that this framework would apply to, we recommend expanding the scope of this statement to include:</p> <p>“... and supporting the adoption of complementary AI education into the curricula and training for other health professionals involved in medical imaging and radiation therapy.”</p>
Line 167 - Regulatory Principles #6	<p>"developed in the context of the skills of the medical practitioners who will ultimately be the end-user".</p> <p>This principle could be enhanced by recognising that the medical professional will continue to choose whether to use or disregard the AI system when available.</p>
<p>Line 179 - Recommendation 1</p> <p>The term “unbiased”</p>	<p>We have a question about whether the term ‘unbiased’ is the best to use here. Bias occurs to some extent with almost any dataset. Furthermore, AI bias is not always problematic and can also be desirable, an opportunity to rectify inequity.</p> <p>It may be worth referring instead to the inclusion of benchmarks that ensure reproducibility and generalisability.</p>
Line 179 - Recommendation 1	<p>The ASA agrees that the inclusion of a statement about "clinically justified tasks" is important.</p>

Line reference/element	ASA comment/recommendation
"clinically justified tasks"	<p>We expect that the scope of AI will be small and specific to start with but will develop over time to include a greater range of patients and pathology.</p> <p>There could be an opportunity in this document to recognise that starting with small tasks will have two positive outcomes. Firstly, current staff can become accustomed to and learn the application of AI. Secondly, it gives more time and more data to create and refine AI applications with larger tasks and greater scope.</p>
Lines 214-217	Consider removing these sentences as it is unclear how they add to or support the position statement.
Line 208 - Recommendation 3	<p>The statements related to Professional liability could be stronger.</p> <p>We recommend considering including greater requirements of systems coming to market to provide education/training and support for the professionals that will use the system.</p> <p>It may also be worth considering that the system manufacturer/suppliers include a statement of their accountability in addition to the limitations and clinical context of the system</p>
Lines 218-220	In addition to the user being aware of the context in which AI devices were trained. We recommend considering also stating that users are aware of the specificity, sensitivity, PPV and NPV of the models they're using, in addition to the general accuracy.
Line 223-225	<p>We recommend that the manufacturer be required to provide access to the reasoning in the system (e.g. through the user interface) to show how an outcome was decided. End-users need to see the inputs/weights to the system to promote AI transparency and understanding.</p> <p>If a misdiagnosis is classified by output, the end-user should be able to see the input data variables and check this information in situ to ensure that these are appropriate.</p>
Line 226 - Recommendation 4	We suggest enhancing this to include the need for a system-wide reporting process for AI incidents and monitoring mechanisms for user reports and complaints, in addition to the manufacturer requirements.
General comments - language/tone	The language of this position statement reads quite negatively in places, focusing on issues/risks/problems that need to be addressed.

Line reference/element	ASA comment/recommendation
	<p>If this was not intended, the arguments of the statement could benefit from recognising the positives and gains that could be expected from the introduction of AI technology and systems.</p>
<p>General comments - the impact of new regulations</p>	<p>AI in medicine is an emerging technology. It may take time to determine the best ways to validate and regulate AI applications.</p> <p>The ASA recommends that the College reflect on the statements of these regulation principles and recommendations to ensure that the timing of the document and content does not risk impairing AI advances and efforts.</p>
<p>General comments – learning systems</p>	<p>It is unclear if this document was developed in consideration of the variety of different machine learning that could be employed to produce AI medical systems</p> <p>There is dominant reference to AI medical systems crafted from training and test populations, known as supervised and semi-supervised learning (Recommendations 3-5). It is unclear if other systems such as unsupervised learning or anomaly detection have been considered.</p> <p>Similarly, it is unclear if other likely future AI architecture in Medical Imaging have been considered. Such as reinforcement learning, where the AI model is released and requires using local population data to finetune and complete the initial AI training process. The model then uses further iterations of local time-series data to update with local issues.</p> <p>The ASA request the College to reflect on these other processes and adjust the statement if needed.</p>