ACPSEM
Australasian College of Physical Scientists & Engineers in Medicine

The Australasian College of Physical Scientists & Engineers in Medicine's Responses to Consultation on
the Proposed *Regulation of Software, Including Software as a Medical Device (SaMD)*

The Australasian College of Physical Scientists and Engineers in Medicine (ACPSEM) would like to provide feedback on the proposed regulatory reforms for medical device software, including software that functions as a medical device in its own right.

We agree with the problems outlined in page 5 of the consultation document and the need for regulatory reform to address these problems. The proposed additions to the essential principles that clarify the requirements for demonstrating the safety, quality and performance of software and SaMD products in Australia are particularly welcome. However, we would like to request further clarification and make specific recommendations on the following points:

1. The new software and SaMD classification rules and their interpretation.
2. The specific regulatory treatment of open-source, freely distributed or "shared" software/SaMD

1. Comments on the new software/SaMD classification rules

The classification rules of *software that processes data to provide information for treatment or intervention in a disease or condition* are of particular interest to radiation oncology medical physicists. Radiation oncology departments make heavy use of myriad software for their everyday operations. For example, it is common for medical professionals to employ several distinct software tools for the quality assurance of a patient's treatment plan. These tools vary in complexity, but many are very simple; they may simply constitute a few lines of code to check the integrity of a file transfer.

Medical physicists rely on these tools to recommend to a clinician whether or not to proceed with a treatment plan. Therefore, under the current wording, each of these software tools could reasonably be interpreted to "[r]ecommend a treatment or intervention for a clinician to decide and administer". Such tools, some of which may have previously been either unclassified or Class I, would now be Class IIa. If so, the new changes could introduce a marked increase in the financial regulatory burden borne by medical software vendors, since:

- their software may either have previously been exempt from inclusion into the ARTG or have attracted lower administrative fees due to lower classification levels, and
- vendors typically have very many separate instances of software or modules that may constitute separate "medical devices" and attract separate associated administrative fees.

The quality and diversity of the software tools available to consumers are highly dependent on the competitive landscape. Increases in regulatory costs should be introduced with caution, since they increase the barriers-to-entry for newly enterprising software developers, protecting incumbents and decreasing competition in an already highly regulated industry. The very risks that the

Suite 7.12 Aero 247, 247 Coward St, Mascot, NSW 2020, Australia
t : +61 (2) 8305 3900 **f :** +61 (2) 9700 8023
e : admin.support@acpsem.org.au **w :** www.acpsem.org.au

regulations aim to mitigate may be counter-balanced by the increased risk posed by a decrease in available high-quality software options.

We ask that some combination of the following recommendations be considered:

- Reword the new classification rules such that simple QA tools are not Class IIa.
- Significantly reduce the charges for inclusion of software in the ARTG, or perhaps consider a tiered/proportionate fee-structure that starts very low and increases according to the commercial size (e.g. by revenue) of the applying vendor.
- Avoid requiring separate entries into the ARTG for software modules that are clearly extensions of existing entries. Ambiguous cases should err on the side of non-separate.

2. Comments on the specific regulatory treatment of open-source, freely distributed or shared software

Increasingly, modern software is available free-of-charge to both institutions and consumers. Software may be freely available via large-scale, collaborative, open-source projects. The open source movement has resulted in very many examples of freely available medical software, many of which are high quality and widely used. Moreover, many institutions develop software in-house. Such software may be shared between institutions through formal agreements (e.g. Memoranda of Understanding) or informally between collaborating professionals. There are myriad other scenarios. This poses a unique challenge to regulators of software. We feel that **current regulations inadequately consider freely shared software, and we would strongly encourage reform in this arena**. The present consultation appears to be an excellent opportunity. However, in the context of the current proposals, we have the following questions/comments:

- Under what circumstances (if any) is freely shared software required to be entered into the ARTG? Does freely sharing constitute "supplying"? Even if there are presently no circumstances in which ARTG entry is required for such software, can future regulatory reforms include a statement to that effect?
- If certain instances of freely-shared software, presently or in the future, are required to be entered into the ARTG, we recommend that providers of free software are exempt from fees or charges associated with ARTG entry. At the very least, substantial reductions should apply. Such fees already pose barriers-to-entry for commercial entities and are likely prohibitive for non-commercial individuals or enterprises.

To manage both the potentially large increase in software required for TGA review along with our proposal to eliminate fees for entering freely shared software into the ARTG, we suggest that the TGA consider outsourcing some portion of the review process. Specifically, one solution might be to implement a two-tiered approach where developers who wish to apply for ARTG entry would first undergo a review process from an independent, TGA-endorsed body. This has at least two advantages: it lightens the TGA's software review burden while exposing software to review by experts who specialize in the software's applications. Particularly for radiation oncology, software is often highly specialized and requires expert knowledge to appropriately assess risks, detect certain logic errors and ensure code is appropriately tailored to the task.

Naturally, any body that is seeking TGA endorsement would need to implement a suitable software review process. Thankfully, we need not reinvent the wheel and can leverage existing guidelines already available from a reputable organisation such as Mozilla, OpenSci or the Journal of Open

Source Software. Perhaps the TGA could implement an accreditation program for budding third-party review bodies, which could be reassessed either at routine intervals or in the event that a minimum software quality that passes third-party review is routinely not being met.

Reponses to questions

1. *Do you support the proposal to change the way medical device software is regulated? Why or why not? If you do not support the proposal, do you have any suggestions for an alternative that would be acceptable to you?*

   We support the proposals to alter the essential principles for medical devices to demonstrate the safety and performance of SaMD and other regulated software. We would welcome the appropriate classification of software and SaMD to better reflect the risk they pose **with the caveat that the likely large associated increase in regulatory burden – especially the fees and charges associated with ARTG entry – should be minimized.** This is particularly important for smaller commercial enterprises and non-commercial entities. The TGA should make provisions for freely distributed software. The present fees and charges for ARTG entry are prohibitively high for these cases, and the TGA should take great care to avoid introducing unnecessarily high barriers to entry for software developers/distributors.

   A suggestion for an alternative that would be acceptable to us would be to implement a fee structure where software that is distributed at no cost to the user also has no cost to the distributor for inclusion within the ARTG. To make this feasible there is the potential to implement a two tiered review process where independent bodies themselves seek accreditation to recommend software to ARTG for review, and to only pass onto ARTG those software packages which will almost certainly pass review. The accreditation of the body itself would come at a cost. Bodies such as ACPSEM could apply to become a reviewing body and provide this service to its college members. See Section 3 above for more details how this could be implemented.

   In this way the cost of inclusion onto the ARTG register could be free for freely distributed software, and could be implemented so as not to significantly increase the burden on the ARTG reviewing body.

2. *What do you consider to be the benefits and disadvantages of the particular proposals for change?*

   Improved clarity in the essential principles will provide a welcome resource for medical software developers to maximize the quality and safety of the software they distribute.

   If the current fees and charges for medical device entry into the ARTG also apply to software, the new classification rules may decrease the availability of quality and safe medical software due to the reduced ability for new developers to enter the market.

3. *Do you believe there will be any unintended consequences arising from the proposed changes?*

   Yes. See our answers to questions 1 and 2 regarding the new classification rules.

4. *What changes would you need to make (if any) to meet the new arrangements? If not, what are the impediments?*

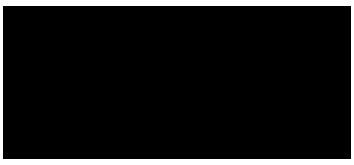
The new arrangements would require further clarification before we can provide an informed answer. For example, would simple QA tools like the ones we described in section 1 be classified as Class IIA? Would the existing fees and charges for medical device entry into the ARTG also apply to software? What constitutes a new instance of software vs an extension of an existing entry? Does freely shared software require ARTG entry?

5. *What financial impact (both costs and savings) would implementing the proposed amendments have for you? If possible please provide a breakdown of the impacts. This information will be used to quantify the financial impact to all affected stakeholders.*

   If our interpretation of the new classification rules is correct, the rules would attract an unacceptably high financial burden, including but not limited to a substantial increase in fees and charges for ARTG entry.

6. *What period would be needed for your organisation to implement the proposed changes? This information will be used to inform any transitional arrangements.*

   This is difficult to say. It may take months for software distributors to consider the implications of the regulatory changes and adjust their operations & projects accordingly. Some projects may be abandoned due to financial unviability. If the proposed changes also apply to software formally or informally shared between institutions, this will take much longer. Institutions would need to decide whether to continue arrangement and bear the regulatory costs, or replace previously shared software through purchases or in-house development. Both scenarios would require planning and business cases to be drafted and executed. We estimate 12-18 months.



Matthew Jennings

ACPSEM SA/NT Branch Chair