

To Whom it may concern,

My name is Simon Parker and I have worked in Medical Device Software for over 20 years. I am providing feedback as a private individual.

Overall, I am in favour of the spirit of the proposed changes to regulations, but I see some issues with details. I've outlined some of the benefits and disadvantages below.

The 3 proposals are:

1. Add detail to the Software Classifications.
2. Make it illegal to import SaMD if not approved in Australia.
3. Add essential principals relating to Software.

Software Classification

Benefits

- Added clarity

Disadvantages

- Includes areas of software that may be of benefit to society, but will not be developed if they need to be classified as Class III. The example I'm thinking of, is where modern big data may provide a way to predict an impending epidemic or provide some other warning. This would be class III software since the effects are big. However, the technologies used for such software (AI, Machine Learning) are very difficult to verify and validate. The benefit could be huge, but the risks of the software malfunctioning are small because a false warning won't hurt anyone. This situation would be better handled by a risk based approach, where the risk of software failure to patients or the public is used, rather than the nature of the decisions to be made.

Import of SaMD

Benefits

- The illusion of safety

Disadvantages

- Impossible to police effectively. Unfortunately, I don't have a solution, however, the effect of this regulation is unlikely to prevent people from using unregulated software if they want to.

Adding Essential Principles

Benefits

- Added guidance as to categories to consider when analysing a system

Disadvantages

- If taken literally, the wording implies a level of development effort that is unrealistic. Specifically, terms like "risks should be minimised" and "best practise cyber security principles" are nice sounding sentences, but are too vague in practise to apply usefully. I appreciate that we all want these risks to be minimised, and that "best practises" are always changing, but there are degrees that it is possible to go to, to minimise these risks, that are unnecessary for most applications. Again a risk based approach should be applied based on the risks to patients of a cyber-security breach.

I hope this feedback is useful.

Regards,

Simon Parker