A FRAMEWORK FOR RISK CATEGORISATION AND CORRESPONDING CONTROLS FOR SaMD

This submission is Professionals Australia's response to the International Medical Device Regulators Forum Working Group's invitation to comment on a possible risk categorisation and control framework for software as a medical device (SaMD)

May 2014

About Professionals Australia

Professionals Australia is an organisation registered under the *Fair Work Act 2009* representing over 25,000 Professional Engineers, Professional Scientists, Veterinarians, Architects, Pharmacists, Information Technology Professionals, Managers, Transport Industry Professionals and Translating and Interpreting Professionals throughout Australia. Professionals Australia is the only industrial association representing exclusively the industrial and professional interests of these groups.

Professionals Australia promotes the views of members on a wide range of policy issues to government, industry and the community.

We have three objectives:

- to provide a strong voice for engineering, science and technology professionals. This includes considering the kind of support, policies and practices at the enterprise and structural levels that will be necessary to create a sustainable engineering, science and technology workforce capable of realising optimal levels of innovation, productivity and competitiveness;
- to play a leading role in encouraging dialogue between industry, government and the higher education sector. This means advocating for investment and structural reforms, building the platforms for collaboration and change and initiating and leading projects to foster collaboration; and
- to promote public understanding of the key role engineering, science and technology professionals play in ensuring Australia's future. This involves influencing public policy and resource allocation decisions and promoting the value of engineering, science and technology to decision-makers and the wider community. We seek to highlight the critical role our members play in enabling productivity and innovation, promoting economic prosperity, protecting the environment, improving human welfare and quality of life and protecting national security. In doing so, we raise the status of these professions and the professionals who work in them.

This Submission is made on behalf of Professionals Australia and also Professional Engineers Australia, Professional Scientists Australia and IT Professionals Australia – each Divisions of the Professionals Australia.

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Foreword

Professionals Australia acknowledges the challenges facing the IMDRF working group in developing a risk categorisation and control framework for SaMD – software as medical device (supplied independently of any specific hardware).

We recognise the indisputable potential for SaMD to enhance the quality of patient care by giving health care providers an enhanced ability to make well-informed clinical decisions.

At the same time however, we recognise the complexity of developing a converged regulatory framework which addresses the potential public health risks posed by SaMD, the rapid evolution of mobile communications technologies and the broad range of settings both within and beyond medical institutions in which those accessing SaMD need to be aware of the quality and risk management issues.

We understand that the framework must provide for determining risk levels, as well as allowing for informed decisions about tradeoffs between risks and potential rewards in both the clinical and home/patient environments. These risks range from breaches of privacy law to diminished management control in institutional clinical settings. Embracing SaMD will require organisations and the community to acknowledge a range of risks and liabilities that were either of less concern or no concern at all with software embedded in existing medical devices.

It is clear that now more than ever we need to put in place appropriate regulatory controls which will protect the public from the potential risks to patient safety and public health posed by SaMD while balancing the enormous potential benefits.

We thank the IMDRF working group for the opportunity to make a very brief submission to this consultation process.

Chris Walton
CEO, Professionals Australia

Comments on the proposed framework

The Submission will provide comments in the format set out in the *Invitation to Comment* (posted at www.tga.gov.au/newsroom/consult-oma-software-imdrf-140512.html) under the heading *Content of Submissions*.

The premise of the framework

Professionals Australia supports the premise of the framework. In our view, the rapidly developing space of SaMD requires regulatory oversight.

Aspects of risk categorisation (technical or otherwise) and corresponding controls that may not be adequately addressed by the framework

The content of the risk categorisation is extensive and complex. However, it would be best to use an analogous structure (and titles) to the existing classification system for medical devices, i.e.

Class I - typically low risk
Class IIa - typically medium risk
Class IIb - typically medium risk
Class III - typically high risk

This will assist with the implementation of the new risk categorisation for SaMDs by providing both healthcare professionals and regulatory agencies with a more familiar framework.

Controls that can be used to assure the quality of software produced

Section 7 of the proposed framework[1] describes well the quality system and standards necessary to manufacture and monitor software over a product life cycle. An appendix listing software design, quality and human factor standards may be beneficial as a reference.

Limitations or suggestions about the framework

The regulatory oversight for SaMDs could become quite onerous considering the vast number and risk levels of SaMDs. Lower risk SaMDs may require a 'self regulation' approach, where the public is provided information from regulatory agencies of the risks surrounding SaMDs to make their own informed decisions on the quality and effectiveness of the software.

How the framework might affect members

Healthcare professionals such as biomedical engineers, healthcare IT professionals and clinicians need guidance from regulatory agencies and information to provide to users of SaMDs. It is necessary for both healthcare professionals and patients to be aware of the risks behind SaMDs and how to assess the quality and effectiveness of software.

Information on what to avoid and who to contact for further advice will allow SaMDs to continue to develop without onerous regulatory oversight and promote 'self-regulation' by users.

Summary

We hope you find our input to this important consultation a useful contribution to developing a framework for risk categorisation and corresponding controls FOR SaMD.

Acknowledgement

Professionals Australia wishes to acknowledge the assistance of Mr. Simon Cowley in the preparation of this Submission.

We also thank Katie Havelberg, Casey Moore and David Nebauer for reviewing the content.

Contact us

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References

[1] International Medical Device Regulators Forum (2014). Software as a Medical Device: Possible framework for risk categorization and corresponding controls, p.19.