29th March 2019

Therapeutic Good Administration
Public submission – Consultation: Proposed regulatory scheme for personalised medical devices, including 3D-printed devices (February 2019)

National Committee on Rehabilitation Engineering Response to the TGA Consultation

Dear Therapeutic Goods Administration,

The National Committee on Rehabilitation Engineering (NCRE), an endorsed specialist group within the Biomedical College of Engineers Australia, represents the profession of Rehabilitation Engineers, who are specialists in Assistive Technology and who work directly and collaboratively with clients to improve health, wellbeing and community engagement.

The NCRE recognises that, in the face of changing manufacturing practices, the regulatory system must evolve to stay current, comprehensive and effective. We are happy to have the opportunity to speak into this process to help create a regulatory framework that achieves the stated proposed benefits. In consideration of the proposed changes the NCRE is supportive of some aspects of the proposal, but feels that other aspects would be detrimental, and that other aspects currently lack sufficient detail in order to properly understand their likely impact.

The NCRE is concerned that the requirement for increased reporting makes no distinction between devices that are Class I (with minimal risk of device adoption) and devices that are of other Classes where the risks are significantly greater. Class I devices should be considered independently of Class IIa and above, reflecting the low risks associated with prescription and usage of Class I devices. There are numerous examples of custom-made Class I medical devices that are used to mitigate health risks (e.g. pressure care supports, orthoses, prostheses), where additional regulation does not make any practical sense, and would not be consistent with *minimising public health and safety risks*, or *minimising unnecessary regulatory burden*.

The NCRE makes the following generalised suggestions in response to the proposals set forward.

- Recognise that increased regulation will typically lead to increased overheads translating to increased costs and may lead to decreased or delayed supply. This may in turn result in increased risk of poor medical outcomes flowing from these delays & cost increases.

- Clarify the scope and depth of proposed reporting requirements for custom-made devices (e.g. an annual summary, a detailed report of each device manufactured, or some middle ground)
- With respect to the proposed IMDRF definitions and as regards to "authorised professionals", clarify who the authorising body is and how authorisation is to be assessed/granted/rescinded.
- Clarify the scope and detail of information necessary for the MDPS assessment, and whether this is differentiated depending on the type of device being manufactured.

Specific Question Responses

1. Do you support the proposal to change the way personalised medical devices are 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?

The NCRE supports some but not all the proposed changes to regulation for personalised medical devices, namely the level of regulation for low risk Class I custom-made and patient-matched medical devices is a concern. Following the consultation process to date, it is clear that the intent is to insure emerging technologies capabilities, such as 3D printing, are appropriately regulated to reduce risk to patient health and safety.

The NCRE propose that Class I medical devices are removed from the scope of the new regulations, and continue under the current framework. Attachments reference further detail from individual rehabilitation engineering centres nationwide.

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

There are significant benefits to the proposed changes, and a need within the industry to provide a framework and regulations around custom-made high-risk medical devices. In particular, implantable 3D printed devices. However, the disadvantages to the disability sector for low risk Class I medical devices is significant. The level of increased regulation could see the custom-made and patient-matched devices no longer financially viable for Assistive Technology suppliers or rehabilitation engineering centres.

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

The NCRE believe that the increased regulation on Class I devices is an unintended consequence of the proposal.

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

See attachments.

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.

See attachments.

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

See attachments.

The NCRE appreciates the opportunity to respond to the TGA's Consultation Paper, and for the opportunity to present our recommendations. The NCRE is happy to engage in further communication in any manner that would be helpful to the TGA on this matter.

Yours Sincerely,

[redacted]

Dr Iain Brown MIEAust CPEng NER **(NCRE Chairperson)** [redacted]
Mr Karthik Pasumarthy
Ms Kristen Morris MIEAust
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Attachment 1: Rehabilitation Technology Unit (RTU) submission to TGA **Consultation Paper**

1. Do you support the proposal to change the way personalised medical devices are 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?

RTU is not supportive of some of the changes in the proposal due to their impact on current Class I custom made devices. The justification given was to address high risk custom devices, and the example given was implantable devices. However, the suggested changes throughout the proposal impact on all low risk Class I devices which is contrary to the proposal's stated purpose.

The proposed regulatory requirements for Class I custom made/ patient matched device would result in a significant administrative and financial burden when the risk associated with these devices is very low compared with the benefit such solutions bring to a patient/client.

RTU suggests that all Class 1 custom made/patient matched devices be exempt from the proposed regulatory requirements and the current Class I custom made device requirements continue to apply for both custom-made and patient matched Class I devices.

Please see the table below for more justification as to why class I medical devices should be exempt from the proposed regulatory changes.

	Text from the TGA proposal	**Page**	**Reasons why RTU is not supportive**	**Suggested Alternative**
1.	*Introduce new definitions for personalised medical devices*	6	The definition of custom made/ patient matched needs to be clarified further. There is always a possibility that an institution/ agency might call the device they manufacture a custom-made device and apply different	RTU suggests that TGA investigate and establish further guidelines for patient matched devices, especially the "envelope" that is being referred to.

			regulations when it is actually patient matched device. Also, it is not clear as to what regulatory requirements apply to patient matched Class 1 devices?	RTU suggests that the current regulatory requirements for Class I custom made devices should continue to apply for both the proposed Class I custom made/patient matched devices.
2.	*Change the requirements for supplying custom-made medical devices in Australia, so that additional information must be provided to the TGA and to patients and, to allow the TGA to inspect manufacturing sites* **Quote from the proposal:** **"*That a manufacturer in Australia, or a sponsor of an overseas-manufactured custom-made device, provides an annual report to the TGA of the custom-made devices it has supplied, and*"**	7	RTU supplies over 2500 custom made class 1 devices / per year. It would be a huge administrative burden to report to TGA annually with all the details that required, it also has significant financial impact to enter these low risk class 1 devices into ARTG. It appears that TGA's proposal hasn't taken into account all of the other low risk Class I custom made devices that are manufactured throughout Australia and the proposed rules for high risk medical devices are being extended for all classes of devices when it should be only for class IIa and above.	RTU suggests TGA continues to exempt Class I custom made devices as risk associated with these devices is very minimal and proposed change should only impact high risk devices and not necessarily class I

3.	*Introduce a framework for regulating medical device production systems which will allow healthcare providers to produce lower risk personalised devices for treating their patients, without the need for manufacturing certification* **Quote from the proposal:** **"***The MDPS is limited to low risk products only, this includes medical devices that are Class IIa and below*"	8	RTU uses 3D printers and CNC Machines for the manufacture of class I custom made devices when there are no commercially available solutions. For example: Rehabilitation Engineering Clinic (REC) which is part of RTU designs and manufactures customised joystick handles (U bars) for powered wheelchairs, some of the advantages of doing this is in house are: • Improving the patient outcome (in this case driving the wheelchair) by providing them a customised joystick handle which facilitate better control of the wheelchair • Cost saving for the department , and quick turnaround are additional benefits. The requirements to be TGA approved MDPS need to be identified. Several facilities across Australia use 3D printers to produce various Class I custom made devices and if TGA were to impose restrictions as to what type of MDPS to be used this would affect and restrict several organisations.	RTU believes that Class 1 devices should be exempt from using the MDPS and the current custom made devices regulatory requirement should apply to proposed custom made/ patient matched Class 1 devices. This will reduce the administrative burden on both TGA as well as the institutions producing Class 1 devices across Australia

			TGA would need to get feedback from across Australia as to what 3D printers can be included in the MDPS. If this is the case TGA might get inundated with many 3D printers to review and include in the MDPS approved list. With the evolution of the new technology TGA would need to be up to date and add new printers to their approved MDPS list to make sure innovation is not inhibited	
4.	*Update the classification rule for medical devices that record diagnostic images so that it includes any device for this purpose and not just X-rays, for example 3D-printed models of patient anatomy* Quote from the proposal: *"Software that records patient diagnostic images should also be captured by this rule"*	9	RTU believes that this statement needs further clarification. There are several systems within the department of health that use diagnostic imaging to produce several Class 1 medical devices. For example: RTU currently uses CAD (computer aided design) software package to make custom orthoses. This process can involve viewing a patient Xray to design the orthoses. Is TGA suggesting that this change be applied only to software used to produce 3D printed models (which could aid in diagnosing a condition or planning a surgery)? If yes, please see the suggestion regarding update the X ray film rule in the next column.	"***5.4 Medical devices intended to record diagnostic images*** *A medical device that is intended by the manufacturer to be used to record diagnostic images is classified as Class IIa. This includes software and anatomical models intended for diagnosis or investigation of the anatomy and production of class IIA and above medical devices*"

			If no, this will have a huge impact on all of the other software that are being used across the Department of Health	

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

   RTU does believe that some changes are required to better regulate the high-risk devices, however as mentioned above these changes should not cover Class I low risk devices

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

   Yes, this could potentially increase the discharge time of hospital patients due to the added administrative burden on Class I custom made devices and could result in large costs to the Department of Health. It will impact significantly on professions such as Orthotics whose main role is the creation and modification of Class 1 low risk devices.

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

   Some of the changes we would potentially need to make would be:

   - Enter all low risk Class I custom made devices into to the ARTG
   - Make changes in our databases to generate reports to TGA
   - Educate relevant authorities of the expected delay in service provision of Class I custom made/patient matched devices

- Apply for additional funding to cope with the administrative and financial burden if the proposed changes take effect.

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 RTU were to include all of the class I custom made devices manufactured into the ARTG this would have significant financial implications as RTU produces over 2500 Class I custom made devices every year. This means that the TGA application fee alone could be well over a million dollars. Some of the current custom-made devices could potentially come under proposed patient matched devices, however there is no regulated MDPS in place and the majority of these class I custom made devices are not even manufactured using 3D printers.

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

   We would suggest 2 years minimum, but more realistically 5 years.

Attachment 2: AT&S' Response to the TGA Consultation Paper

Assistive Technology & Seating (AT&S) is a Rehabilitation Engineering Centre operating as a service of the Northern Sydney Local Health District.

Specific Question Responses

1. Do you support the proposal to change the way personalised medical devices are 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?

AT&S is broadly supportive of the proposed changes for Class IIa devices and higher but questions whether the same regulatory requirements are reasonable for Class I devices. Some of the proposed changes require further explanation to fully appreciate the amount of overhead that would be required to satisfy the regulatory requirements. For custom-made Class I devices, this could quickly become an unnecessary burden resulting in higher device costs.

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

AT&S feels that the proposals are a reasonable response to changes in current manufacturing capabilities. New capabilities, such as the growth of the additive manufacturing field, have lowered the barrier to entry in the area of manufacturing. This lowered barrier represents a risk to the consumer (of lower quality products), however this risk needs to be weighed against the risk of disrupting the supply of Class I custom-made devices due to unnecessary regulatory demands.

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

AT&S believes that increasing the regulation on Class I devices may undermine the TGA's stated aims to minimise public health and safety risks and minimise unnecessary regulatory burden.

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

This will depend on what the precise reporting requirements of the new system would be. It would certainly result in time that is currently allocated to clinical interaction being necessarily reassigned for fulfilling regulatory reporting. This will reduce the effectiveness of the service and may increase the waiting list, which may in turn have adverse implications for client health.

The expected standards for a prospective MDPS are unclear, this may require significant changes to manufacturing practices and environments.

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.

As a public health service, no costs are currently borne by the client, however the service would need to absorb any cost associated with compliance. The value of these costs will depend on the specific requirements of compliance, which require clarification.

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 timeframe would depend on the specific amount of detail and volume of reporting required by the proposals (which are not currently clearly defined). Likely timeframe would be between 1-3 years.