ACPSEM
Australasian College of Physical Scientists & Engineers in Medicine

The Australasian College of Physical Scientists & Engineers in Medicine's Responses to Consultation on
Proposed regulatory scheme for personalised medical devices, including 3D-printed devices

The Australasian College of Physical Scientists and Engineers in Medicine (ACPSEM) would like to provide feedback on the proposed regulatory scheme for personalised medical devices including 3D printed devices.

While we appreciate the regulatory scheme is largely focused on surgical applications and implantable medical devices we believe there needs to be some guidance for lower risk radiotherapy applications. This would ensure that these applications are not regulated to such an extent that valuable, safe applications of 3D printing are rendered unavailable to patients who would benefit. This submission comprises a case study, recommendations and additional comments. The key issues from the point of view of radiation oncology medical physicists are:

1. Clarification on the use of hobbyist 3D printers with robust quality assurance for low risk medical applications
2. We suggest introducing exemptions from most regulatory oversight (including ARTG listing and MDPS conformity assessment evidence) for Class I low risk medical devices, if the devices are produced under suitable local expertise such as qualified medical physicists or qualified biomedical engineers
3. In most cases 3D printing is replacing and improving upon "hand made" devices that suffer most of the same risks
4. Increased regulatory burden would render some applications of 3D printing in radiotherapy too costly and time consuming to be clinically feasible

We argue that the 3D printed custom devices in radiotherapy are largely just replacing a very similar handmade version of the same device, which is used in the same way, made from similar material (particularly so in the case of thermoplastic material) and have similar risks associated.

The 3D printed version has the advantages of being more accurate and personalized to the patient, and also can be made from a patient image without the requirement of the patient's presence. So it saves time during the simulation process and reduces the length of time the patient needs to be present and **often removes a procedure which may be stressful for the patient.**

Clinical example on the use of 3D printing for radiotherapy bolus applications

Background

Many radiation oncology departments are currently using or in the process of developing techniques utilising an inexpensive consumer grade 3D printer to create custom radiotherapy bolus for external use on intact skin. This is a very low risk application of 3D printing, with stringent quality assurance processes to be in place.

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Radiotherapy bolus is used to negate the skin sparing effect in megavoltage therapy beams and is typically made from materials exhibiting water equivalent behaviour in radiotherapy beams. Conventional bolus can lead to undesirable air gaps between the bolus and the patient surface, especially for regions of high curvature. These air gaps can cause an under dose of radiation to the skin. This is problematic when the skin forms part of the clinical treatment region and can result in poorer tumour control and associated patient outcomes. The primary advantage of a customised 3D printed bolus is it can greatly reduce air gaps compared to conventional bolus. An additional advantage is that it can reduce the number of patient visits for mould fitting as it can be created using the CT scan acquired as part of the normal radiotherapy treatment planning process.

Certified medical physicists have expertise to test the acceptability of 3D printed materials for use in radiotherapy procedures and it would be disappointing to see patient outcomes affected by unnecessary regulatory burdens and fees.

Response to Questions

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?*

No, we believe that the proposed regulations for personalised medical devices are too burden-some for certain low risk applications. We do support the proposed regulations for high risk personalised medical devices such as customised patient implants.

We would suggest introducing exemptions from most regulatory oversight (including ARTG listing and MDPS conformity assessment evidence) for Class I low risk medical devices, if the devices are produced under suitable local expertise such as qualified medical physicists or qualified biomedical engineers.

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

An advantage of the proposals is a reduction in the risk of patient harm arising from unregulated high risk custom made medical devices such as internal implants. The disadvantages are that it may stifle innovation and that lower risk applications may be needlessly swept up by this reform. The original regulation for customised medical devices was created with low risk devices in mind. We understand the need for additional regulation for high risk devices, however we believe the previous regulation remains adequate for low risk applications.

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

In many cases we don't believe that radiation oncology departments would be able to continue using existing printers, as manufacturers of MDPS will need to obtain conformity assessment evidence for their system. Most centres are currently using an inexpensive consumer grade printers, which are more than adequate for the task but they were not purpose built to create a medical device. We're doubtful that what some might consider to be a hobbyist 3D printer meets the description of a MDPS, as it is not intended to produce a medical device. If the printer manufacturer were required undergo conformity assessment certification we think it is unlikely that they would be willing & able to do so. The costs associated with a more sophisticated system may see the technique abandoned.

For a health system already under financial strain, it is unlikely that the necessary financial and human resources will directed towards meeting the additional regulatory burden and the new techniques may be discarded. This would see the continued use of inferior techniques such as bolus used without customisation or customised bolus created using 'handmade' techniques. Alternatively, customised bolus may be purchased from manufacturers at a much greater cost of production. Although some manufacturer lobbyists would be greatly pleased with this result, this is an unnecessary contribution to the rising cost of health care

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 comment fully on this. For example, what constitutes a medical device production system? Would a consumer grade printer meet the description of a MDPS, as it is not intended to produce a medical device? If not, than an entirely new MDPS would need to be purchased and clinically commissioned.

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.*

Additional financial costs arising due to ARTG listing fee and ongoing annual renewal. Costs of new MDPS if applicable. Staffing costs associated with meeting additional regulatory requirements and application processes.

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

If the proposed changes were to go ahead as is then business cases across the health sector would need to be drafted to justify the addition resources required to meet the regulations whilst maintaining the service of custom low risk devices for use in radiotherapy. Therefore, we would estimate 12-18 months

<u>Other Suggestions</u>

Further thought is required on the concept of a MDPS: "*A medical device production system (MDPS) is a collection of the raw materials and main production equipment intended to be used by a healthcare provider, or healthcare facility, to produce a specific type of medical device at the point of care, for treating their patients."* Under this broad definition any manufacturing practice that produces customised medical devices would be considered a MDPS, even those with low technological sophistication.

We don't think the following statement on page 8 in reference to a MDPS is adequately explained "*all components must be validated as a production process to consistently produce the intended medical device with the use of the supplied instructions.*" There are no details provided as to how all components would be validated, to what level and who would be responsible for this validation. In the case of customised medical devices developed on site there are no instructions supplied. This may be suitable for already well establish techniques but not so for emergent technologies.

Further comments

Many centres would not use the 3D printed bolus if they were required to perform extra quality procedures to meet the TGA requirements as this would be much too onerous relative to the cost and time of our current procedures. This would be a step backwards for the accuracy of radiotherapy delivery.

A “case for specific exemptions from regulatory oversight given the very low risk nature of the device” would be a good solution.

In general, 3D printed devices would rigorously tested, and therefore suitability would be identified prior to use, in the same way as current handmade devices are. This would assure that the size/shape/density consistency of the print were correct, and likewise any unsuitable prints would be identified before use.

Please do not hesitate to contact ACPSEM if further questions or queries arise. The College’s point of contact is [redacted]

Yours Faithfully,

ACPSEM