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Department of Health
Therapeutic Goods Administration

Proposed regulatory changes related to personalised and 3D printed medical devices

Consultation paper

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TGA Health Safety
Regulation

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Introduction

Purpose and scope

The purpose of this consultation paper is to:

- propose changes to the current medical device regulatory framework in Australia to ensure adequate regulation of personalised medical devices such as those being enabled by 3D printing.
- seek feedback from individuals, industry, healthcare practitioners, patients and patient representatives to identify issues and address any unintended consequences to inform the proposal and the regulatory amendment process.

This document is focused on regulatory considerations for medical devices that are manufactured for particular patients. It does not cover the technical considerations for designing, manufacturing and testing such devices. These are devices that are currently captured under the custom made device definition¹, and its corresponding exemption², as well as devices that are referred to in the definition of manufacturer³ as devices already supplied but intended to be assembled or adapted to suit an individual. This document includes 3D printed medical devices manufactured for a particular patient, but it is also applicable to such devices manufactured through other methods.

Background

Why change?

The increasing use of 3D printing for medical applications is raising questions globally about the adequacy of the current medical device regulatory frameworks to mitigate risks to patients, and to meet requirements for health care providers and manufacturers. The widespread application of this manufacturing technology to medical devices was not envisioned in the early 1990s when the Global Harmonisation Task Force documented the principles that underpin device regulation in Europe, Australia, Canada and other jurisdictions.

Over the past two decades, rapid advances in computing technology and materials science have driven exponential change in medical imaging technology, manufacturing technology, and (as a result) medical device technology. For example, the idea that a hospital would be able to use a 'printer' to manufacture an implant for a particular patient's anatomy would have been considered impossible in the not too distant past; but it is a reality today.

Australia, and other jurisdictions, introduced exemption provisions for regulating custom-made medical devices with the intention to cover special cases where commercially available mass produced products were inadequate for the needs and requirements of a particular patient. The Australian provisions for custom made devices exempt them from the requirement of being included in the Australian Register of Therapeutic Goods (ARTG). As a result, manufacturers and sponsors are exempt from the associated regulatory requirements such as inspections of manufacturers' premises and the requirement for third party certification. The provisions were based on the premise that affected devices would largely comprise low risk products such as

¹ Therapeutic Goods (Medical Devices) Regulations 2002, Dictionary

² *ibid*, Schedule 4, Item 1.5

³ Therapeutic Goods Act 1989, s41BG(3)

glass eyes, prosthetic limbs, prescription lenses, etc. This assumption regarding risk classification was accurate at the time the current custom-made medical device provisions were introduced, but the situation has evolved.

Now regulators are faced with a very different environment. Technology has made personalised devices, including implantable devices for particular patients, within reach on a much greater scale. Consequently, ever growing numbers of patients are receiving higher risk classification medical devices to meet their particular needs, under custom made device exemptions. It is important to note that, like conventionally manufactured mass produced medical devices, 3D printed mass produced medical devices are not custom-made and are regulated under the existing risk based framework.

High risk implantable devices are generally manufactured under strictly controlled conditions and are subject to rigorous premarket testing and regulatory oversight to ensure that they comply with the essential principles for safety and performance. However, strict regulatory oversight is not the case with the majority of similarly high risk 3D printed implants in Australia, which are currently captured under exemptions for custom-made medical devices.

For further background information please refer to the following appendices:

- [Appendix 1 - Background on 3D printing](#)
- [Appendix 2 - Medical applications of 3D printing](#)
- [Appendix 3 - The international perspective](#)
- [Appendix 4 - 3D printing FAQs](#)

The current regulatory environment

In Australia, as in many other parts of the world, the medical device regulatory framework was developed before 3D printed medical devices were in clinical use. Under the current framework any objects that meet the definition of a Medical device, including those that are manufactured with the use of 3D printing, are subject to regulation. For mass produced 3D printed devices there is no difference in regulatory requirements compared with conventionally manufactured devices. In this case, for devices above Class I, the manufacturer must have a Quality Management System that is certified by the TGA or European notified body; and the manufacturer must have evidence that each device model it produces complies with the relevant essential principles for safety and performance. This evidence must be reviewed by the TGA or European notified body. The manufacturer is required to undergo annual onsite inspections by the certifying agency. Medical devices of this type must be included in the Australian Register of Therapeutic Goods prior to supply and their manufacturers must have procedures in place for post-market monitoring and reporting and for recall actions if required.

Devices that meet the definition for custom-made, however, whether 3D printed or otherwise manufactured, have different requirements. At the current time, 3D printed implants or surgical tools that are made for a particular patient or physician, fit the Australian definition for custom-made devices. As such, they are exempt from being included in the ARTG and they must meet the requirements under the conformity assessment procedures for custom-made medical devices specified in the regulations⁴.

The custom made conformity assessment procedure requires a manufacturer of a custom made medical device to undertake four activities. A manufacturer must:

⁴ Clause 7.2 of Schedule 3 and Regulation 10.3 of the Therapeutic Goods (Medical Devices) Regulations 2002

- prepare a statement about the device and its compliance with the essential principles;
- prepare documentation for the device in relation to its design production and intended performance;
- ensure that the manufacturing process results in the device complying with its design and intended performance; and
- notify the Secretary of adverse events or potential adverse events, or recalls of the device.

There is no requirement to provide any information to the patient, and apart from adverse event notification, there is no requirement for interaction with the TGA or other certifying body in this conformity assessment process.

After they begin supplying custom made devices in Australia, manufacturers (or sponsors of imported custom made devices) must notify the TGA. The information required to be notified consists of the manufacturer's (and sponsor's if applicable) name and address and a description of each kind of device including GMDN code and classification. There is no requirement to notify the manufacturing method so, unless it is provided in the description, it is not known whether a device is 3D printed. The current custom made database includes the full spectrum of device classifications from Class I to Class III, and includes implantable devices.

There is no requirement for third-party or regulatory certification of the manufacturer or of the evidence held in support of a custom-made device. The framework allows for the TGA to request information from these manufacturers; however, it does not provide the power for the TGA to enter and inspect the premises where custom made manufacturing occurs. This is in contrast to manufacturers of devices not covered by the custom made exemption, who by virtue of being included in the ARTG, are subject to the condition of allowing the TGA to enter and inspect any premises which deal with an included device⁵, even if the manufacturer's certification is from an European notified body.



- Custom-made medical devices are exempt from inclusion in the ARTG.
- They are required to comply with applicable Essential Principles but they do not require regulatory or third party oversight of their evidence of compliance with the essential principles.
- They may be supplied with a justification for non-compliance with applicable essential principles.
- Their manufacturers do not require any QMS certification, or other third party oversight.
- Manufacturers and sponsors of custom-made devices are **not** exempt from post market surveillance and reporting requirements.

Requirements for custom-made devices include compliance with applicable essential principles (Schedule 1 of the Regulations) however, if for some reason, some aspects of the relevant Essential Principles cannot be complied with, then a justification for the noncompliance must be

⁵ s41FN Automatic Conditions of Inclusion

documented. Therefore, it is possible that a custom-made device will not comply with all relevant essential principles.

To demonstrate compliance with the essential principles for custom-made devices, the TGA's current expectation is that the regulatory requirements for an equivalent risk-classification device, that is not custom made, should be applied to the custom made devices. For example, a joint implant that is not custom-made, would be a Class III device required to comply with the conformity assessment procedures specified in Part 1 of Schedule 3 of the above-mentioned Regulations. This would include manufacturing within a Quality Management System that meets the requirements specified in ISO 13485, and also the application of relevant ISO standards (or equivalent state of the art) for aspects such as sterility, biocompatibility and risk management to demonstrate compliance with the Essential Principles.

Regardless of the pathway to market, custom made or conventional, the manufacturer and sponsor are not exempt from their post market obligations for surveillance and reporting of certain things, including malfunctions, injury, and potential injury related to the device, to the TGA.

Another aspect of the current regulatory framework that may be relevant to the regulation of 3D printed devices is a current exclusion from the responsibilities of being a manufacturer. Currently if a person assembles or adapts a supplied device for an individual patient, without changing the intended purpose of the supplied device, that person is excluded from the responsibilities of being the manufacturer. There is the potential for improper interpretation of this provision as regards raw materials that have been included in the ARTG and which are intended to be formed into final devices. The potential for confusion about this provision comes from the fact that the amount of assembly or adaptation that is allowed under this provision is not explained. Because of this lack of clarity, there is the potential for extending the improper interpretation of this provision to the raw materials intended for 3D printing patient specific devices. This exclusion requires further explanation to ensure it is interpreted correctly.

Proposals for regulatory change

Considering the lack of third party or regulatory oversight of custom made devices and their manufacture, and the increasing supply of high risk devices under the custom made device exemption, there are concerns that the current regulatory framework does not adequately mitigate risks to patients receiving implantable devices that fit the definition of custom-made.

Implantable devices manufactured on a commercial scale, such as patient specific devices enabled by 3D printing, should be subject to regulatory oversight to ensure that compliance with the essential principles has been established, and is maintained through certified manufacturing processes. The following specific cases for change are intended to ensure risks associated with personalised medical devices are adequately mitigated.

Proposal 1: New definitions for personalised devices

The current regulatory framework does not include an adequate vocabulary for devices that are intended for a particular patient. Custom made device is the only currently defined term in this group and it is clear that there are other categories that require regulatory consideration.

By taking a stricter interpretation of what constitutes a custom-made device it would be possible to ensure 3D printed patient-specific implants were not included in this category. This is the approach taken by the USFDA and, as a result, these devices are subject to normal pre-market requirements according to their classification level.

What would change?

The definition of custom made device

A proposal for consideration is to make the definition of custom made device more specific so that it is clear that custom made devices are not intended to be manufactured through a routine process on a commercial scale but instead are for cases involving rare patient conditions or anatomy where there is no commercially available alternative. It is also proposed that it is made clear that the design of the custom made device is under the responsibility of the health care professional who makes the request, as specified in the definition of custom made device in Europe.

The following changed definition is proposed:

custom made medical device - means any device

- that is specifically made in accordance with a written request of any person authorised by Australian law by virtue of that person's professional qualifications as a healthcare provider which gives, under that person's responsibility, specific design characteristics; and
- that is intended for the sole use of a particular patient exclusively to meet their individual conditions and needs; and
- for which there is no commercially available alternative medical device.

Mass produced devices which need to be adapted to meet the specific requirements of any professional user and ***patient specific devices*** shall not be considered to be custom-made devices.

The addition of some new definitions

The following new definitions are proposed:

- ***customised medical device*** - a medical device that is supplied by a manufacturer with a specified intended purpose and that must be adapted or assembled, in accordance with the manufacturer's validated instructions, to suit an individual patient prior to use
- ***patient-specific medical device*** - a medical device based on a standard device template model that is matched to a patient's anatomy using techniques such as scaling of the device based on anatomic references, or by using the full anatomic features from patient imaging, and which is produced through a process that is capable of being validated
- ***personalised medical device*** - a device intended for a particular patient which could be a custom made, customised, or patient specific medical device
- ***mass produced medical devices*** - medical devices that are produced in production runs or batches of the same product.
- ***medical device production system*** - a collection of products, including specified raw materials, that is intended to be used by a health care practitioner to produce a finished medical device and that may include the

input of a digital patient image file.

The system output must be validated with the specified components. The classification of the system is determined by the classification of the finished device.

What would this mean?

Excluding 3D printed patient specific medical devices from the custom-made definition would result in these devices being regulated under the existing framework for medical devices. This is based on the risk classification level of the device and is designed to have increasing oversight as the risk level increases. For example, non-invasive 3D printed prostheses would be class I devices and would not require third party oversight, while a joint implant device would be class III and require both design and manufacturer QMS certification by a third party.

Devices that continue to be captured under the new definition of custom made would be those that are for cases involving rare patient conditions or anatomy where there is no commercially available alternative and may span the full spectrum of risk classifications. However, it is anticipated that the number of high risk custom made devices would be significantly decreased.

Questions for consideration – Proposal 1

- Is the proposed definition for custom made device clear enough; or should additional measures be taken such as:
 - Should the number of custom made devices that a manufacturer or sponsor can supply in one year be limited? The FDA limits this number to 5 per year in the USA, a country whose population is more than 10 times that of Australia.
 - Should the TGA implement an application and approval process for the use of a custom made device? This is the approach taken by Health Canada.
- Do you have any other comments or suggestions about the proposed definitions?
- Do you have any other comments or suggestions for alternative or additional strategies?



Proposal 2: Changes to the custom made conformity assessment procedure

At present the Australian regulations state that a manufacturer of a custom made device must prepare a written statement about the device, including whether or not it complies with the essential principles. The regulations only require the manufacturer to keep this statement; while under the current requirements in Europe, the manufacturer or an authorised representative must also provide this information to the patient. In addition, the current regulatory requirements for custom made devices only require that a notification is given to the TGA by the manufacturer or sponsor of the kinds of custom made devices being produced or supplied. The TGA may request information about the devices; however, the legislation does not provide a

power for TGA to enter and inspect manufacturing sites for custom made devices. Additionally, in Australia the manufacturer is only required to keep documentation about a custom made device for 5 years after supplying the device. This is an inadequate period of time for an implantable device; and in other jurisdictions, such as Europe, this period is specified as 15 years.

What would change?

It is proposed to change the conformity assessment procedure for custom made devices to require:

- that the manufacturer's statement about a custom made device is provided to the patient receiving the device. This is the current requirement in Europe.
- that the TGA be allowed to enter and inspect custom made device manufacturing sites, in accordance with the authority it has to inspect all other medical device manufacturers.
- a manufacturer in Australia or sponsor of custom made devices to provide an annual report to the TGA of the custom made devices it has supplied.
- documentation about an implantable custom made device to be maintained for a minimum period of 15 years, the current specification of a 5 year retention period is inadequate.

What would this mean?

This change would result in greater transparency for a patient receiving a custom made medical device. Making the statement about the device available to the patient would ensure they understood the custom made nature of the device and could also improve the informed consent process. The other changes would provide greater transparency to the TGA about the manufacture and supply of custom made medical devices in Australia, providing the TGA the ability to monitor quality, safety and performance of these devices.

Questions for consideration - Proposal 2



- Are there any issues or unintended consequences that may arise out of these proposed changes to the custom made conformity assessment procedure?
- If there are issues, can you provide suggestions for addressing them?
- Do you have any other comments or suggestions for alternative or additional strategies?

Proposal 3: Changes to the definition of manufacturer

Customised devices

Under the current definition of manufacturer, a person is not the manufacturer of a medical device if the person assembles or adapts the device for an individual patient; and the device has already been supplied by another person; and the assembly or adaptation does not change the purpose intended for the device (this is the production of a **customised device** as defined in proposal 1).

A case where this is currently applied is in dental crowns where the crown material is included in the ARTG. It has been interpreted that the dentist assembles and/or adapts the crown material for an individual patient and does not require conformity assessment certification for a manufacturing activity. The regulation is applied to the manufacturer and sponsor of the crown material. Whether or not this is in the spirit of the original intention of this provision is unclear, as there are no specified criteria for what constitutes “assembly or adaptation [that] does not change the purpose intended for the device”.

This provision requires clarification because any assembly or adaptation of a device under this provision should be in accordance with validated instructions from the original manufacturer. It is clear then, that the manufacturer’s liability for the product is limited to that which is in accordance with their instructions. Any activities outside of what has been specified by the original manufacturer may impact on compliance with the essential principles and would add risk. This situation would therefore require the person undertaking the assembly or adaptation activities to assume the liability for the product and all of the responsibilities of the manufacturer, including conformity assessment.

Clarifying this exclusion is relevant to 3D printed devices because there are now options for a dentist to 3D print crowns. There is the potential for the same interpretation that is currently being applied to crown material in the ARTG to be applied to raw materials for 3D printing. The TGA does not believe it is sufficient to only regulate the raw material for a 3D printer. 3D printing is more than assembling or adapting a device for a particular patient; it is a manufacturing process that has an impact on the finished devices’ compliance with the essential principles. Some additional clarification around this provision is required.

What would change?

To clarify the entities that hold responsibilities as a manufacturer it is proposed to change the definition of manufacturer of medical devices⁶.

It is proposed to clarify the current provision:

- (3) However, a person is not the manufacturer of a medical device if:
- (a) the person assembles or adapts the device for an individual patient; and
 - (b) the device has already been supplied by another person; and
 - (c) the assembly or adaptation does not change the purpose intended for the device by means of information supplied by that other person, on or in any one or more of the following:
 - (i) the labelling on the device;
 - (ii) the instructions for using the device;
 - (iii) any advertising material relating to the device;
 - (iv) technical documentation describing the mechanism of action of the device.

⁶ s41BG of the *Therapeutic Goods Act 1989*

by specifying that:

the assembly or adaptation must be in accordance with validated instructions provided by the manufacturer of the device to be adapted; and that, if an individual modifies a device already placed on the market or put into service in such a way that compliance with the essential principles may be affected, they shall assume the obligations incumbent on manufacturers.

What would this mean?

This change would clarify that producers of *customised devices* (as in the proposed definition) are not manufacturers, and are not required to meet the regulatory requirements of a manufacturer.

A new paradigm for health care facilities and practitioners as manufacturers

It is becoming more common for health care practitioners and hospital laboratories to manufacture 3D printed medical devices, but it is currently not common for these entities to hold regulatory certification as manufacturers. This is mainly a result of the current custom made device exemption.

If *patient specific devices* (as defined in proposal 1) are excluded from the definition of custom made, then their manufacturers will be subject to meeting the requirements of the ordinary pre-market conformity assessment procedures, including certification and the ongoing post market requirements.

An option for regulatory change is to consider the potential for applying special arrangements for some circumstances, such as allowing low risk medical devices to be 3D printed in certain locations such as dental offices or hospital laboratories, with different conformity assessment provisions.

For higher risk devices, such as patient specific implants, the current conformity assessment provisions, commensurate with the devices' risk classification would still apply. Please see the discussion under "If a hospital laboratory 3D prints medical devices is it a Manufacturer?" in Appendix 4 for further information about these requirements.

What would change?

It is proposed to add a new exclusion from the responsibilities of being a manufacturer. This would apply to health care practitioners or hospital laboratories that use *medical device production systems* (as defined in proposal 1 above) that are included in the ARTG to produce medical devices of risk classification Class IIa and lower for use in treating their own patients. In these cases the manufacturer of the automated system would retain the responsibilities as the manufacturer of the finished device produced by the system. This arrangement would require the manufacturer of the system to hold conformity assessment certification, rather than the healthcare provider who uses the system.

However, if the healthcare provider or hospital used the *medical device production system* to produce devices for supply beyond treating their own patients, they would be considered to be the manufacturer of the devices and would be required to meet all obligations of a manufacturer including conformity assessment certification.

What would this mean?

This change would allow hospitals and healthcare practitioners to use approved **medical device production systems** to produce medical devices of Class IIa and lower for treating their own patients without being required to meet the regulatory requirements of a manufacturer.



Questions for consideration – Proposal 3

- Are there any issues or unintended consequences that may arise out of these proposed changes to the definition of manufacturer regarding **customised devices**?
- Are there any issues or unintended consequences that may arise out of these proposed changes regarding the use of **medical device production systems**?
- If there are issues, can you provide suggestions for addressing them?
- Do you have any other comments or suggestions for alternative or additional strategies?

Proposal 4: New classification for anatomical models and digital 3D print files

The regulation of anatomical models for investigation of the anatomy and/ or diagnosis also requires consideration for change. This includes both digital 3D print files and the physical 3D printed models that are physical versions of these digital files. Under the present classification rules, these are Class I non-invasive devices.

Currently, there is a special classification rule⁷ that states:

5.4 Non-active medical devices intended to record X-ray diagnostic images

A non-active medical device that is intended by the manufacturer to be used to record X-ray diagnostic images is classified as Class IIa.

Due to changing technology for patient imaging, and the advent of medical device 3D printing, this rule should be updated. Anatomical models that are manufactured by 3D printing of a patient's digital images for consideration by a specialist in diagnosing a condition or planning a surgery, are also medical devices that are used to record diagnostic images (but not necessarily from an X-ray source). It is reasonable to think that these anatomical models should require the same regulatory oversight, to mitigate the risk of inaccuracy, and to ensure they are a true representation of the patient's anatomy with sufficient quality for their diagnostic purpose. Software that records patient diagnostic images should also be captured by this rule.

⁷ Rule 5.4 of Schedule 2 of the Therapeutic Goods (Medical Devices) Regulations 2002

What would change?

It is proposed that the existing rule for X-ray film as Class IIa should be changed to the following:

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.

What would this mean?

Manufacturers of anatomical models would be required to hold appropriate conformity assessment evidence for a Class IIa device. This would not apply to hospitals or healthcare practitioners if they used a **medical device production system** to produce the anatomical models for treating their patients, and the **medical device production system** was included in the ARTG.

Manufacturers of software that is intended to be used to record patient imaging that will be used for diagnosis or investigation of the anatomy will be required to hold appropriate conformity assessment evidence for a Class IIa device.

Questions for consideration – Proposal 4



- Are there any issues or unintended consequences that may arise out of the proposed change to the classification of anatomical models and software?
- If there are issues, can you provide suggestions for addressing them?
- Do you have any other comments or suggestions for alternative or additional strategies?

Proposal 5: New arrangements for devices with human material

3D ‘bioprinting,’ or printing of patient specific implants that incorporate human origin material, is increasing and likely to be on a commercial scale in the near future. Some jurisdictions, including Canada, Europe and the USA, recognise medical devices with human origin material. In contrast, the TGA legislation specifies that any product that comprises, contains or is derived from human cells or human tissues is a biological and is regulated through the biologicals framework. This arrangement is not ideal for 3D printed implantable scaffolds with human materials; as they are analogous, from a design, engineering, production and assessment perspective, to current implantable scaffolds with medicine, or animal origin material. The current arrangement in Australia, that labels these products as biologicals, means these devices are likely to be subject to different regulatory pathways in other jurisdictions. The TGA’s business processes and fee structures for medical devices are better suited for the primary assessment of these 3D printed products.

What would change?

To ensure the most efficient and effective assessment of these products, it is proposed that medical devices that contain as a component, but that are not wholly comprised of, human origin material are not biologicals, but are Class III medical devices. Regulation 4.1 should be amended to require conformity assessment for medical devices that contain a biological (human origin) component. Accordingly, the fee schedule should be amended to include a fee for the assessment of the biological component during the design examination process. This would allow better alignment with other jurisdictions, such as Europe and Canada, which allow human material in medical devices; and would allow for the possibility of abridged assessment in accordance with current procedures. It is proposed that this change should apply to both viable and non-viable human origin components, because the TGA has the in-house expertise to evaluate both as a component of a medical device.

What would this mean?

This change would mean that a medical device incorporating materials of human origin would be regulated as a medical device and not as a biological, more closely aligning with other jurisdictions. These kinds of medical devices would be subject to TGA conformity assessment.



Questions for consideration – Proposal 5

- Are there any issues or unintended consequences that may arise out of the proposed change to the pathway for medical devices that incorporate materials of human origin?
- If there are issues, can you provide suggestions for addressing them?
- Do you have any other comments or suggestions for alternative or additional strategies?

Question for consideration – General

- Do you have any comments or suggestions for alternative or additional strategies regarding the regulatory framework as it applies to personalised medical devices or 3D printing in the medical device sector to ensure that it adequately addresses risks to patients?

Appendix 1 – Background on 3D printing

Basic premise of 3D printing

The basic premise of 3D printing is the concept of additive manufacturing or building an object by adding layer upon layer of raw material. This is accomplished without a mould and is the opposite of conventional subtractive manufacturing where an object is formed by cutting a shape from a larger piece of starting material.

In simple terms, the required elements for 3D printing are: a raw material that can be adhered to itself, a source of energy for causing the adherence such as light or heat, computer controlled movement of the energy source and/or the raw material, and a computerised “pattern” for the desired object.

The 3D printing method of manufacture has some distinct advantages over traditional manufacturing. For example, because a computerised pattern is used rather than physical moulds, it is possible to easily adjust the pattern between each manufacturing run, even between each individual device. In addition, the inner and outer surfaces of a solid object are built simultaneously with 3D printing. This allows the manufacture of single-piece geometries that are impossible with conventional manufacturing methods. An example of this is the production of hollow spaces inside of a solid object. With conventional manufacturing methods the design of the interior channels would be limited by the necessity to remove the shape from a mould, or else would require the joining together of two or more pieces; with 3D printing a single-piece object with the desired design can be achieved.

Different types of 3D printing and different materials used

The following is from the US Energy Department (<https://energy.gov/articles/how-3d-printers-work>).

Over the years, the 3D printing industry has grown dramatically, creating new technologies (and a new language to describe the different additive manufacturing processes). To help simplify this language, ASTM International -- an international standards organization - released standard terminology in 2012⁸ that classified additive manufacturing technologies into seven broad categories. Below are quick summaries of the different types of 3D printing (with material extrusion explained in the previous section).

Material Jetting: Just like a standard desktop printer, material jetting deposits material through an inkjet printer head. The process typically uses a plastic that requires light to harden it (called a photopolymer) but it can also print waxes and other materials. While material jetting can produce accurate parts and incorporate multiple materials through the use of additional inkjet printer nozzles, the machines are relatively expensive and build times can be slow.

Binder Jetting: In binder jetting, a thin layer of powder (this can be anything from plastics or glass to metals or sand) is rolled across the build platform. Then the

⁸ <https://iss.isolutions.iso.org/obp/ui#iso:std:iso-astm:52900:ed-1:v1:en>

printer head sprays a binding solution (similar to a glue) to fuse the powder together only in the places specified in the digital file. The process repeats until the object is finished printing, and the excess powder that supported the object during the build is removed and saved for later use. Binder jetting can be used to create relatively large parts, but it can be expensive, especially for large systems.

Powder Bed Fusion: Powder bed fusion is similar to binder jetting, except the layers of powder are fused together (either melted or sintered -- a process that uses heat or pressure to form a solid mass of material without melting it) using a heat source, such as a laser or electron beam. While powder bed processes can produce high quality, strong polymer and solid metal parts, the raw material choices for this type of additive manufacturing are limited.

Directed Energy Deposition: Directed energy deposition can come in many forms, but they all follow a basic process. Wire or powder material is deposited into thin layers and melted using a high-energy source, such as a laser. Directed energy deposition systems are commonly used to repair existing parts and build very large parts, but with this technology, these parts often require more extensive post processing.

Sheet Lamination: Sheet lamination systems bond thin sheets of material (typically paper or metals) together using adhesives, low-temperature heat sources or other forms of energy to produce a 3D object. Sheet lamination systems allow manufacturers to print with materials that are sensitive to heat, such as paper and electronics, and they offer the lowest material costs of any additive process. But the process can be slightly less accurate than some other types of additive manufacturing systems.

Vat Photopolymerization: Photopolymerization -- the oldest type of 3D printer -- uses a liquid resin that is cured using special lights to create a 3D object. Depending on the type of printer, it either uses a laser or a projector to trigger a chemical reaction and harden thin layers of the resin. These processes can build very accurate parts with fine detail, but the material choices are limited and the machines can be expensive.

Reliance on software

3D printing is a digital technology and, as such, is reliant upon the correct application of software to achieve successful outcomes. 3D printing utilises two major software components, one is a 3D software model of an object and the other is a translation of the object software model into printer-specific software that controls the build. A range of different software platforms are available for both of these components and the process of translating the object model to a printer-ready state is not always straightforward. Sometimes additional software platforms are required to add final corrections or refinements to the translated model prior to printing.

The pattern, or build file, for a 3D printed object is essentially a map for the printer's computer that controls the movement of the energy source and/or the raw material. The build file for a 3D printed object can be thought of as the coordinates on a digital grid for a number of adjacent 2D slices of the desired object.

The quality of a 3D printed object is heavily dependent upon the correct application of complex software interfaces.

Use of medical imaging

Computerised (or digital) medical imaging methods have become common over the past few decades, and these imaging modalities lend themselves extremely well to providing the software image models for use in 3D printing.

Modern Computed Tomography (CT) acquires a volume of data in a helical (or spiral) path, and this data can then be reconstructed in various planes, including 2D and 3D representations of structures.

Magnetic Resonance Imaging (MRI) generally acquires images 'slice by slice' through an area of interest in a patient's body. These slices can be assembled to provide a 3D image on a computer screen, or can easily be used to create a software pattern for a 3D printed object.

Use and interoperability of image data

In 1993, the American College of Radiology (ACR) and the National Electrical Manufacturers Association (NEMA) developed a global information technology standard. The Digital Imaging and Communications in Medicine (DICOM) is a standard⁹ for handling, storing, printing, and transmitting information in medical imaging.

DICOM includes a file format definition and a network communications protocol. It is used worldwide to store, exchange, and transmit medical images, and has been central to the development of modern radiological imaging. DICOM includes protocols for image exchange (e.g., via portable media such as DVDs), image compression, 3-D visualization, image presentation, and results reporting.

Scan data in DICOM format is not directly compatible for use in 3D printing; however, there are a number of proprietary and also free, 'open-source' software packages that can convert DICOM data to 3D printer files.

Technical considerations

Although the concept of 3D printing is a simple one, its successful implementation for any precision parts or for any parts made from metal is extremely complex. In addition to the software considerations, there are many parameters that must be very tightly controlled in order to achieve the desired result. This is especially true in the case of implantable device manufacture where not only does the manufacturing process itself require careful control, but also the quality of the materials used and the condition of the environment where the process is undertaken. This is to ensure that unknown sources of contamination or harmful substances are not introduced to the device.

The large numbers of variables that are involved in the 3D manufacturing process mean that it is difficult to predict the performance of the materials used in the finished product. The step-wise addition of material layers in 3D manufacturing inherently introduces directionality into the structure, which is known to affect mechanical properties of the material. Behaviours of plastics and metals fabricated with conventional manufacturing processes are well characterised through many years of testing and research data. In comparison, the performance parameters (including mechanical properties) of 3D printed materials are not as well understood.

A technical discussion of the 3D manufacturing process is beyond the scope of this document. However, a recent publication from the USFDA¹⁰ that provides more detailed discussion on both 3D printed device design and manufacturing, and testing considerations is a valuable background reference document.

⁹ <http://dicom.nema.org/>

¹⁰ [Technical Considerations for Additive Manufactured Devices, FDA Draft Guidance for Industry and FDA Staff, 10 May 2016](#)

Appendix 2 - Medical applications of 3D printing

Anatomical models

The adaptability of medical imaging to 3D printing makes it possible to reproduce a tangible model of a patient's anatomy. For example, in a MRI scan of a patient's chest, the imaging equipment "takes a picture" of a "slice" of the patient's body at the level of interest. The target for the next image is a slice in the same direction but adjacent to the initial image. A series of images of slices of the body is produced, with each slice being directly adjacent to the one before, and continuing until the structure of interest (e.g. lungs, heart) has been captured. The thickness of a slice is determined by the resolution of the imaging equipment, i.e. what level of detail the "camera" can "see." This series of images can then be "assembled" by the imaging computer software and displayed as a 3D image on a monitor to provide a view of structures inside a patient's body.

The same series of images can be translated from the image display software into a software pattern for a 3D printer. Different tissues in the body have different identifiable properties that are represented uniquely in the software images. This allows different structures to be targeted and selected for printing. For example, cardiac tissue can be targeted for the production of a heart model; and bone may be targeted for an orthopaedic model.

3D printed anatomical models can be used for different purposes, for example:

- **Planning of surgeries** – For complex surgical repairs of anatomical defects, a 3D printed model of the target, the heart for example, can allow the surgeon to physically see and hold a 3D object that may be difficult to conceptualise through 3D image display software. Internal structures of the heart will be present in the model so that cross-sectioning the model at the appropriate location will allow the defect to be seen in full scale. This may allow diagnosis of structural anomalies and may also allow planning of the surgical approach prior to the patient being under anaesthesia potentially shortening the duration of surgeries, and potentially improving outcomes.
- **Functional testing platforms** – In the pre-clinical lifecycle stage of a medical device its design requires validation and verification testing. Many of these tests are conducted using fixtures or equipment that is designed to mimic anatomical features, for example silicone tubing used in delivery simulation testing of an intravascular catheter. 3D printed anatomical models have the ability to improve the credibility of the test results in predicting device performance in a human by providing realistic anatomical geometries for testing.
- **Training** – Realistic anatomical models, including those representing defects in anatomical structures, can be produced with 3D printing and used in the training of health care providers. The use of 3D models and simulated procedures during training is already occurring; however, using 3D printing adds the ability to ensure true to life anatomy is represented in the models, rather than an idealised artist's version on a computer screen.



Figure 1 - Abdominal aortic aneurysm model for aortic endograft (stent-graft) testing and training ¹¹

- Design/fitting of medical devices prior to delivery or implantation** – 3D printed models can provide access to a relevant part of a patient’s anatomy, making it is possible to fabricate a medical device that will fit the unique features of the patient. This method was used in the dental industry prior to the advent of 3D printing through casting techniques in situ in the mouth. It is now possible to access internal structures to design an orthopaedic fixation, for example, prior to a surgical procedure.

Non-invasive prosthetics

3D printed externally-worn prosthetics represent a low risk classification for medical devices, as they are not invasive. However, for amputees and others, the appropriate quality and variety of devices that artificially replace missing parts of the body have a significant impact on mobility and functioning, and respectively on the safety and quality of life.

Prosthetic limbs are typically custom designed and custom-made for each patient. Properly fitted/customised upper or lower limb prostheses are expected to closely replicate a residual or incomplete limb or stump for fitting of the attachment; and also should properly fit with the prosthetic that replaces a missing body part. While significant enhancements have been made in terms of prosthetic components and socket design, achieving proper fit for each individual can still be a challenge (for example, due to the fact that most people experience changes in the size and shape of their stump from day to day, or over a period of time).

Therefore, manufacturing devices using patients’ scanned body images and 3D printing, versus the currently widely used moulding method, may provide better flexibility and opportunities for creating devices that are better tailored to specific anatomical characteristics of individuals.

Surgical tools and guides

3D printing technology lends itself to objects with limited production runs, including single object runs with dimensional variations. This has particular applicability to the production of specialised instruments, including those for use in surgeries. Tools with unusual shapes that are difficult or expensive to manufacture with conventional methods, tools that are specifically designed to facilitate a surgery for a particular patient, tools that are specifically designed for use by a particular surgeon can all be realised with the use of 3D printed manufacturing.

¹¹ <https://www.embodi3d.com/custom-3d-printing-for-medical-device-development/> accessed 2/07/2017



Figure 2 - Glenoid and a patient-specific surgical guide for reverse total shoulder arthroplasty (rTSA)¹²

Dental devices

In the dental field, intra-oral 3D scanners and their resulting digital models of mouth structures have made it possible to introduce 3D printing technology¹³. Printers are currently being used to produce low risk devices such as implant surgical guides, orthodontic aligners and retainers, dentures, night guards and temporary crowns. The scale of 3D printers for these devices, and the materials used, are such that they can be intended for use within a dental office. The expense of the machines may limit them to higher volume dental labs; however, as the technology becomes more common, the prices are reducing.

In addition to the above, there are some higher risk implantable devices designed for use in maxillofacial surgery that are based on individual patient images. These are typically made from metal in a more “industrial” 3D printing manufacturing process that also requires critical post print processing steps. These types of printers are typically in a dedicated manufacturing facility that specialises in this work.

Implantable orthopaedic devices

3D printing is currently being used to create implantable orthopaedic medical devices. These include mass produced devices, which may come in a range of sizes, but are not tailored for individual patients, and also include patient-specific implants.

Examples of mass produced 3D printed orthopaedic implants that are currently supplied in Australia are acetabular cups for hip replacement surgery. Using 3D printing it is possible to achieve a surface on these cups that mimics human bone and promotes bony tissue in-growth. These medical devices are classified as Class III under the current framework and are thus

¹² <https://pbs.twimg.com/media/DDM7Wo3XkAAfiNR.jpg> accessed 2/07/2017

¹³ It is worth noting that 3D scanners have been in use for more than 10 years to generate data for producing dental crowns. The crowns themselves have not been produced with 3D printing but rather with a solution using an in-office, miniaturised, traditional manufacturing technology - computerised numerically controlled (CNC) milling. This is a cut-away process, not additive manufacturing, but represents a similar level of automation for restorations manufactured in a dental surgery.

subject to design examination certification by the TGA or a notified body; and in addition, their manufacturers must hold regulatory QMS certification.

Orthopaedic implants are also being produced using 3D printing based on digital models that come from patient imaging. These patient specific implants are produced in a repeatable process, within a given range of sizes; however the digital model that is used to generate instructions for the printer is changed for each print to represent a particular patient.

Bioprinting

Bioprinting is a term applied to 3D printed scaffolds that incorporate materials of human origin. One of the main goals of bioprinting is to produce implants that will allow the regeneration of native tissue such that the patient is not left with a permanent artificial implant. This is accomplished by 3D printing a scaffold from a material that is capable of both replacing the functionality of an anatomical structure, and sustaining living human cellular material, before being resorbed and replaced in the body by native tissue. There are many examples of bioprinting in the research stage, such as meniscus implants, vascular implants, bone grafts; and it will not be long before they are available for commercial use.

Appendix 3 - The international perspective

Brazil

Brazil's regulator, ANVISA, conducted a seminar in October 2016 to discuss regulatory gaps for patient specific medical devices. In February 2017 ANVISA took a decision to inform manufacturers of an intention to regulate, although drafting of documentation has not yet commenced. The policy will include requirements for pre-market authorisation for companies manufacturing patient specific devices. The policy will capture all patient specific medical devices regardless of the manufacturing method; that is, it will be broader than 3D printed devices.

ANVISA's position is evolving as it considers regulation of 3D printers and raw materials used to manufacture implantable patient specific devices. In particular, ANVISA is considering establishing requirements for manufacturing plants or hospitals manufacturing patient specific devices.

ANVISA has expressed support of TGA's active engagement with this topic and will support any future IMDRF work items that support harmonisation of regulation in this area.

Canada

Canada also does not currently have any published guidance on 3D printed medical devices. As in Australia, these kinds of devices may fit within Canada's definition of custom-made medical devices. However, unlike Australia where only notification is required, Canada has an application process for the use of custom-made devices. This gives Health Canada the ability to determine whether a device is appropriate for the custom made pathway under their Special Access Programme. The definition of custom made in the Canadian Medical Devices Regulations SOR/98-282 is:

custom-made device means a medical device, other than a mass-produced medical device, that:

- (a) is manufactured in accordance with a health care professional's written direction giving its design characteristics;
- (b) differs from medical devices generally available for sale or from a dispenser; and
- (c) is
 - i. for the sole use of a particular patient of that professional, or
 - ii. for use by that professional to meet special needs arising in the course of his or her practice.

The Special Access Programme considers requests from Health Care Professionals for access to unlicensed medical devices for emergency use, and also grants authorizations for custom-made medical devices required for unique patient circumstances.

Medical devices authorized under Special Access do not undergo the same level of scrutiny required to obtain a medical device license or an authorization for investigational testing.

Accordingly, authorization through Special Access does not constitute an opinion that a medical device has been assessed and found to be safe, effective or of high quality for general use.

The process for applying for a custom-made medical device is essentially the same as applying for Special Access. The Health Care Professional must, however, include documentation that describes his or her written direction to the manufacturer for the design and construction of the custom-made medical device.

According to Part 2 of the Canadian regulations, the application for a custom-made device approval must provide the following information:

- The diagnosis, treatment or prevention for which the device is required,
- The reasons the device was chosen,
- The risks and benefits associated with its use,
- The clinical reasons why the procedure could not be accomplished using conventional treatment or a licensed device that is available for sale in Canada,
- The known safety and effectiveness information in respect of the device,
- A written undertaking by the HCP that the professional will inform the patient for whom the device is intended of the risks and benefits associated with its use,
- The manufacturer's directions for use of the device.
- In the case of a custom-made medical device, a copy of the Health Care Practitioner's written direction to the manufacturer giving the design characteristics of the device.

EU

The EU has not published guidance on 3D printed medical devices. As in Australia, these devices, when made for particular patients, fit the current EU definition of custom-made medical devices.

The new EU Medical Devices Regulation 2017/745, which was published on 22/02/2017 and was signed into law in April 2017¹⁴, added the following statement (in bold) to the definition for custom-made device (Article 2, Definitions, Paragraph (3)):

'custom-made device' means any device specifically made in accordance with a written prescription of any person authorised by national law by virtue of that person's professional qualifications which gives, under that person's responsibility, specific design characteristics, and is intended for the sole use of a particular patient exclusively to meet their individual conditions and needs.

However, mass produced devices which need to be adapted to meet the specific requirements of any professional user and **devices which are mass produced by means of industrial manufacturing processes in accordance with the written prescriptions of any authorised person shall not be considered to be custom-made devices;**

¹⁴ [Regulation \(EU\) 2017/745](#) of the European Parliament and of the Council of 5 April 2017 on medical devices

This new phrase is not further defined in the MDR; and as guidance has not yet been published, it is unclear whether this is intended to capture 3D printed medical devices based on patient imaging data.

Another new addition to the European MDR is a requirement for third party oversight of the manufacture of some custom-made devices. Under Article 52 (8) Manufacturers of Class III implantable custom-made devices require third party assessment and certification of their quality management system by a notified body prior to marketing their devices. There is an exemption for health institutions that manufacture if a fairly lengthy list of conditions is met.

Japan

In September 2015, Japan's regulatory agency (PMDA) released some technical guidance about 'evaluation criteria for orthopaedic surgical implants manufactured using 3-dimensional layering technology'. The document is only available in Japanese at this time; an English translation is not publically available. It provides technical guidance for medical devices that use 3D printing technology but does not address the regulatory pathway for such devices.

Japan is experiencing an increase in the number of 3D printed and patient specific medical devices. PMDA have confirmed they have some pre-market applications for patient specific 3D printed medical devices but none are yet approved.

USA

The USFDA has moved ahead of other jurisdictions to begin addressing the regulatory challenges posed by 3D printing. In July 2012 the USFDA legislation was amended¹⁵ to include stricter requirements for custom-made devices¹⁶. Much of the definition that allowed a custom-made device exemption in the USA was similar to that in Australia however in 2012, the following requirements were added:

- (1) The device is for the purpose of treating a *"sufficiently rare condition, such that conducting clinical investigations on such a device would be impractical;"*
- (2) the production of the device must be *"limited to no more than five units per year of a particular device type"*; and
- (3) a manufacturer is required to submit an annual report to FDA on the custom devices it supplied.

By limiting custom-made devices to rare conditions and to 5 units per year, the FDA has excluded many of the implants that are currently produced through 3D printing for a specific patient from the custom-made device exemption.

The FDA has also published guidance for 3D printed medical devices. The document was released as a draft for comment in May of 2016, and is still in draft status. The guidance document introduces the concept of "patient-matched devices", which is relevant for 3D printed implants, and states:

¹⁵ <https://www.federalregister.gov/documents/2016/10/12/2016-24438/medical-devices-custom-devices-technical-amendment>

¹⁶ See US FDA guidance document at <https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm415799.pdf>

Patient-matched devices can be based on a standard-sized template model that is matched to a patient's anatomy.

Patient-matching can be accomplished by techniques such as scaling of the device using one or more anatomic references, or by using the full anatomic features from patient imaging.

Note that while patient-matched or patient-specific devices are sometimes colloquially referred to as, "customized" devices, they are not custom devices.

The regulatory changes introduced by the FDA in 2012 ensure that 3D printed "patient matched" implants or surgical tools are not exempt from standard premarket requirements for safety and effectiveness.

The FDA has also taken the position that the software for anatomical models requires pre-market notification as shown in the following:

[Anatomical models are] treated much in the same way as a visible printed record of the anatomy (21 CFR 892.2040 Medical Image Hardcopy Device). Software has been cleared through the 510(k) pathway that allows for segmentation of 3D patient scans, for example CT or MRI scans, to be converted to a 3D representation of the anatomy.¹⁷

¹⁷ Di Prima et al, Additively manufactured medical products – the FDA perspective, May 2016, [https://www.researchgate.net/publication/303750500 Additively manufactured medical products - the FDA perspective](https://www.researchgate.net/publication/303750500_Additively_manufactured_medical_products_-_the_FDA_perspective) [accessed 2/07/2017].

Appendix 4 – 3D printing FAQs

Is a 3D printer a medical device?

Whether or not an object is a medical device is dependent upon its intended purpose according to the manufacturer. If the intended purpose fits the definition of a medical device given in the *Act*, then the item is a medical device. In the current usage of 3D printers in the medical field, they are unlikely to meet the definition of a medical device themselves, even though they are used to manufacture items that do meet the definition of a medical device.

In other words, in the current usage, and under the current regulatory framework, 3D printers are generally considered as manufacturing equipment and not themselves medical devices.

Are 3D printed medical devices ‘custom-made’?

If an object fits the definition of medical device and fits the definition of custom-made under the current framework, it is considered to be a custom-made medical device. Implantable devices that are made on the basis of a particular patient’s anatomical dimensions, such as those produced through 3D printing from medical imaging, in general, fit into the Australian definition of a custom-made medical device. 3D printed medical devices that are mass produced in a similar way to conventionally manufactured medical devices are not custom-made.

A custom-made medical device is one that:

- (a) is made specifically in accordance with a request by a health professional specifying the design characteristics or construction of the medical device; and
- (b) is intended:
 - a. to be used only in relation to a particular individual; or
 - b. to be used by the health professional to meet special needs arising in the course of his or her practice.

“Specifying the design characteristics or construction of the medical device” is not further defined in the Regulations; therefore, it could be considered that clause (a) is satisfied simply by the provision of the patient’s imaging by the health professional to the implant manufacturer and requesting a 3D printed implant.

Under the current regulatory framework, 3D printed medical devices based on specific patient dimensions or specific characteristics specified by a health professional do fit the definition of custom-made; whereas, uniformly mass produced 3D printed devices do not.

Are 3D printed anatomical models medical devices? If so, are they custom-made?

This depends on the intended purpose of the anatomical model according to its manufacturer. If the anatomical model is printed from CT scans of a particular patient, and it is intended to be used in the diagnosis or investigation of the anatomy of the patient, then the model would fit the

definition of a medical device. The same consideration for custom-made status applies to anatomical models that fit the definition of medical device. Under the current framework, they are captured in the definition of custom-made.

What is a ‘customised’ device?

While the term customised is not defined in the current Australian medical device legislation, it is sometimes used to refer to medical devices that are assembled or adapted for a particular patient by an entity other than the original manufacturer. This act, of assembly or adaptation, does not constitute manufacturing if the device has already been supplied by another person; and the assembly or adaptation does not change the purpose intended for the device as specified by the original manufacturer. The intention is that devices such as eyeglasses, dental fillings, and thermoformed splints should be in this category.

From a regulatory perspective the role of the entity, who adapts a supplied product for an individual, is not identified. Also, the level of assembly or adaptation, of a device already supplied, that can occur before a person becomes the manufacturer is not specified. Regardless, the process of 3D printing is more than assembly or adaptation, and so the entity undertaking this process is the manufacturer and resulting devices are not ‘customised.’

Can a 3D printed implant be included in the ARTG?

Mass produced 3D printed devices are already included in the ARTG. There is the potential under the current framework for patient specific 3D printed devices, that are now considered custom-made, to be included in the ARTG. This is the same approach the FDA has taken with their “patient matched” definition.

Depending on the device, it may be possible to consider that the device is of a kind that is not exempt and the ‘custom-made’ aspect really consists of producing ‘variants’ of the device (for Class III implants); or other devices of the same “kind” (for Class IIb implants). This could be applied in circumstances where it would be possible to demonstrate that validation/verification testing on samples, which bracketed the worst case configurations, would ensure that the full range of products complied with the relevant essential principles. The potential for using this approach would depend on several factors including the design and production methods for the device. If this case were applicable, then it would be possible to apply the conformity assessment procedures under Schedule 3 Parts 1 - 5, whichever were relevant, that would lead to certification.

If a hospital laboratory 3D prints medical devices is it a manufacturer?

There is no provision in the legislation to exempt a hospital that produces medical devices from the responsibilities of being the manufacturer, if it supplies the devices under its name. It is possible that production could occur in a hospital as a manufacturing site for another manufacturer, if that manufacturer could demonstrate its control over the hospital manufacturing process. In either case, the manufacturer is required to apply the relevant conformity assessment procedure to the devices it produces.

In general this means, for devices that are not custom made, the manufacturer (either the hospital or the manufacturer that controls the hospital manufacturing site) must have a quality

management system that complies with ISO 13485¹⁸ and must ensure its devices comply with the relevant essential principles. The application of the quality management system ensures that devices are manufactured in appropriately controlled conditions, by appropriately trained staff, under validated processes and that they are released for supply only after all in-process quality control measures have been completed. Compliance with the essential principles is usually demonstrated through the application of international standards such as ISO 10993¹⁹, ISO 14971²⁰, and ISO 11135²¹. Once the relevant pre-clinical testing has been performed and clinical evidence has been compiled, manufacturers are required to obtain conformity assessment certification from the TGA or a European notified body, and have their devices included in the ARTG.

In addition to the above, a manufacturer is responsible for conducting post market activities such as monitoring and reporting certain events to the TGA. This includes reporting:

- any malfunction or deterioration in the characteristics or performance of the device
- any inadequacy in the design, production, labelling, instructions for use or advertising material for the device
- any use of the device that has led to, or potentially may lead to, the death or serious deterioration in the health of the patient or user of the custom-made device
- any information relating to technical or medical reason for a malfunction or deterioration of a custom-made device that has led the manufacturer to recover the device

Are there international standards for the strength and performance of 3D printed objects?

ISO and ASTM International have jointly crafted the *Additive Manufacturing Standards Development Structure*, a framework which will help meet the needs for new technical standards in this fast-growing field. This covers standardization in the field of Additive Manufacturing (AM) concerning processes, terms and definitions, process chains (Hard- and Software), test procedures, quality parameters, supply agreements and other fundamentals.

“This coordinated approach to standards development in AM is crucial to building out robust standards at all levels,” said Joerg Lenz, collaborative projects coordinator at Electro Optical Systems and chair of ISO Technical Committee 261 on additive manufacturing (ISO/TC 261). “Standards developers can see how this new structure allows them to come together, leading to further innovation in fields like medical, aerospace, and automotive, and also other benefits such as a platform for certification activities.”

From: <http://www.todaysmedicaldevelopments.com/article/additive-manufacturing-iso-astm-materials-101316/>

This structure was jointly approved by committees F42 and ISO/TC 261 after a meeting in Tokyo. This reflects progress under the Partner Standards Developing Organization agreement

¹⁸ ISO 13485 Medical devices -- Quality management systems -- Requirements for regulatory purposes

¹⁹ ISO 10993-1 - Biological evaluation of medical devices

²⁰ ISO 14971 Medical Devices -- Application of Risk Management to Medical Devices

²¹ ISO 11135-1 – Sterilization of Health Care Products – Ethylene Oxide

signed five years ago between the two globally-respected standards development organizations. In creating this document, both groups reviewed past, existing, and planned standards development efforts.

The new structure does not confine the scope of work for any standards organization but provides a framework in which the majority of standards needs can be met. A companion guidance document is also being developed to accompany this structure.

This framework is part of the Partner Standards Development Organization (PSDO) cooperation agreement that was approved in 2011 by the respective governing bodies of ISO and ASTM in consultation with the ISO national member body where ASTM has its legal seat (ANSI).

Are there other standards that apply to 3D printed medical devices?

Yes, any standards that are applicable to medical devices in general are applicable to medical devices manufactured using 3D printing technology. For example, in order for conventionally manufactured medical devices to demonstrate compliance with the essential principles there are many medical device standards that provide appropriate guidance, methodology and testing procedures. A specific case is the globally accepted standard for biocompatibility of medical devices, the ISO 10993 series. As the state of the art, the TGA considers that this standard would be applied to demonstrate compliance with the essential principles that are relevant to biocompatibility.

Do the current regulatory requirements adequately protect consumers?

Irrespective of whether 3D printing technology is used, the current regulatory requirements may need to be re-balanced in order to address the risks posed by implantable devices that fit the definition of custom-made. In the framework for devices that are not custom-made, implantable devices undergo rigorous pre-market scrutiny including verification of their evidence of compliance with the essential principles of safety and performance and certification of their manufacturer's quality management systems.

Custom-made implants in the current framework are not subject to third party oversight of pre-market evidence of safety, quality and performance (e.g. clinical evidence, biocompatibility testing, etc.). Historically, custom-made medical devices did not, in general, represent higher risk category therapeutic goods. In the very few instances where this was the case, their numbers were very limited. Custom-made medical devices were historically intended for special cases where commercial products were inadequate for a particular individual.

The advent of 3D printing implants on a commercial scale, with each implant made to a particular patient's scan measurements, has changed the individual vs population risk question for custom-made devices under the current broad definition.

Are 3D printed implants with body tissues medical devices?

Under the current arrangements within the Therapeutic Goods Act 1989, if a product contains any material of human origin then it is defined to be a 'biological', and is regulated under the Biologicals framework. Therefore, medical devices that contain any tissues, cells, or other human-derived materials are not covered under the Therapeutic Goods (Medical Devices) Regulations 2002. This includes 3D printed implants that may incorporate human materials.

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