3D Systems Perspective Comes from:

- User / service provider and creator of software and 3d printing technology.
- 25 yrs of servicing medical models (1st 3d printed model 30 yrs ago on SLA).
- Have printed over 100,000 models in our history.
- Registered and regulated medical device company.
- Play a part in the solution of over 60 cleared 3d printed medical devices in the market.
- Safety and quality are our biggest focus.
Types of Anatomical Models

Training and Simulation Models
Generic teaching, training and research models not associated with the treatment of a specific patient.

Visualization Models / Unaltered Anatomical Models
Models used to visualize all manner of anatomy to be used for surgical planning, and patient consent. Can still be used for diagnosis.

Surgical Rehearsal, Surgical Reference Models, and Sterilizable Unaltered Models
More sophisticated / regulated:
- Intraoperative reference and planning or rehearsal.
- Altered anatomical models showing mirrored, reconstructed, or perfected anatomy.
- Sterilized unaltered anatomical models referenced in surgery.
- Biomimetic materials for simulation of procedures using the model.
Types of Anatomical Models

**Training and Simulation Models**

Not a concern for industry, SIG or FDA.

**Visualization Models / Unaltered Anatomical Models**

- Made more clear in last guidance document but has created a slippery slope of regulations and challenges with managing end user (surgeons).
- Validating them for their intended use and listing them under product code HWT (orthopedic template for clinical use) made sense.
- For those who list anatomical models today, still done under this product code.

**Surgical Rehearsal, Surgical Reference Models, and Sterilizable Unaltered Models**

- Consistently regulated as medical device.
- Often under product code HWT as above.
Localization of 3D Printing Technology
Why are we here today?
Technical Considerations for Additive Manufactured Devices

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.


You should submit comments and suggestions regarding this draft document within 90 days of publication in the Federal Register of the notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fisher Lane, rm. 1061, Rockville, MD 20852. Identify all comments with the docket number listed in the notice of availability that publishes in the Federal Register.

For questions regarding this document, contact the Division of Applied Mechanics at (301) 796-3501, the Division of Orthopedic Devices at (301) 796-3650, or Matthew Di Prima, Ph.D. at (301) 796-2507 or by email matthew.diprima@fda.hhs.gov. For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-335-4709 or 240-402-8010.


https://www.fda.gov/medicaldevices/productsandmedicalprocedures/3dprintingofmedicaldevices/default.htm
Continued Guidance

### Maintaining safety and efficacy for 3D printing in medicine

Andy Christensen¹ and Frank J. Rybicki²,³,*

**Introduction**

3D printing has revolutionized a phase of strong growth, providing new opportunities. The integration is successful, 3D printing of clinical procedures is now an option for academic medicine. The results are individualized, and the device is used in a single clinic. This can be done at a cost that has not been possible with 3D printing. The Center for Devices and Radiological Health (CDRH) at the US Food and Drug Administration (FDA) has reviewed and updated devices more than 10 years [1]. An important shift is happening towards point-of-care manufacturing in emergency settings.

**Keywords:** 3D printing, 3D printing, Medical device, 3D printing.

**Correspondence**
Department of Radiology, University of Vienna, Vienna, Austria
E-mail: andy.christensen@univie.ac.at

**Introduction**

Additively manufactured medical products – the FDA perspective

Matthew Di Prima¹, James Coburn¹, David Hwang¹, Jennifer Kelly¹, Akm Khairuzzaman¹ and Laura Ricles³,⁴

**Introduction**

Additive manufactured medical products have been rapidly developed and utilized in many clinical settings as a result of the 2016 publication of the "Additively Manufactured Medical Products - The FDA Perspective." The perspectives in this publication (the "FDA Perspective") and other newly published documents provide a framework for understanding the regulatory considerations for additively manufactured medical devices.
Reality is Still

• Regulatory and quality requirements for design, manufacture and use of anatomical models is still not clear.

• It is perceived that industry is regulated differently than hospitals for the same products.

• The 3d printing industry (hardware and software) were not developed with the intent to produce medical devices.

• An adverse event from industry or hospital setting will hurt the entire 3d printing community.
Elements of 3D Systems’ QMS

Conform to 21CFR820, ISO13485, AS9100 highlights including:

- Controls
  - Design, Process, Validations, Documentation,
    Records, Device History
- Training
- Continuous Improvement
- Audits
- Product Lifecycle Management

Controlled through an automated review and electronic system encompassing hundreds of process level SOPs, operational level WI, forms, design history files and training documents.
Scope of a Regulated Product

- Material Handling
- Shipment & Delivery
- Product Design
- Final Inspection & QC
- Production

* includes software and hardware *
# Materials Testing – Biocompatibility

ISO 10993: Biological Evaluation of Medical Devices

<table>
<thead>
<tr>
<th>Device Categories</th>
<th>Biological Effect</th>
<th>Other&lt;br&gt;4</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Initial</td>
<td></td>
</tr>
<tr>
<td>Contact Duration</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A- Limited [≤ 24 hrs]</td>
<td>&amp;</td>
<td>&amp;</td>
</tr>
<tr>
<td>B- Prolonged [&gt;24 hrs to ≤30 days]</td>
<td>&amp;</td>
<td>&amp;</td>
</tr>
<tr>
<td>C- Permanent [&gt;30 days]</td>
<td>&amp;</td>
<td>&amp;</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Body Contact</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Skin</td>
<td>A</td>
<td>&amp;</td>
</tr>
<tr>
<td>Surface Devices</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mucosal Membranes</td>
<td>A</td>
<td>&amp;</td>
</tr>
<tr>
<td>Breached or Compromised Surfaces</td>
<td>A</td>
<td>&amp;</td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>&amp;</td>
</tr>
<tr>
<td></td>
<td>C</td>
<td>&amp;</td>
</tr>
<tr>
<td></td>
<td>A</td>
<td>&amp;</td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>&amp;</td>
</tr>
<tr>
<td></td>
<td>C</td>
<td>&amp;</td>
</tr>
<tr>
<td></td>
<td>A</td>
<td>&amp;</td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>&amp;</td>
</tr>
<tr>
<td></td>
<td>C</td>
<td>&amp;</td>
</tr>
<tr>
<td></td>
<td>A</td>
<td>&amp;</td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>&amp;</td>
</tr>
<tr>
<td></td>
<td>C</td>
<td>&amp;</td>
</tr>
<tr>
<td></td>
<td>A</td>
<td>&amp;</td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>&amp;</td>
</tr>
<tr>
<td></td>
<td>C</td>
<td>&amp;</td>
</tr>
<tr>
<td>External Communicating Devices</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood Path, Indirect&lt;br&gt;3</td>
<td>A</td>
<td>&amp;</td>
</tr>
<tr>
<td>Tissue /Bone/Dentin</td>
<td>A</td>
<td>&amp;</td>
</tr>
<tr>
<td>Communicating</td>
<td>A</td>
<td>&amp;</td>
</tr>
<tr>
<td>Circulating Blood&lt;br&gt;3</td>
<td>A</td>
<td>&amp;</td>
</tr>
</tbody>
</table>

*Note*: The table above summarizes the biological effects associated with different device categories and contact durations, as per ISO 10993: Biological Evaluation of Medical Devices.
Product Testing – Sterility

- Cleaning
- Bioburden
- Sterilization Method
- Product Material and Geometry
- Sterility Assurance Level

Sterility

Product Processing and Handling
3D Systems Summary

• As software and hardware developers (and users) of the technologies to make anatomical models, we want to be a part of the solution.
• Cheaper and faster are always demanded, but accuracy, quality and patient safety are our biggest focus.
• Thank you for inviting us to the discussion.