3D Printing Medical Devices at Point of Care

CDRH Additive Manufacturing Working Group
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How it is being used at PoC

3DP at PoC Conceptual Framework

• Availability of innovative products

• Safety and effectiveness regardless of how the product is manufactured

• Proper quality control so that product specifications are met and patient risk is minimized

• 3DP PoC personnel and organizations have necessary knowledge and expertise

• Clearly identified responsible party for activities during the medical device total product life cycle
Guiding Principles for Discussion

• Employ a risk-based approach
• Device specification are identified regardless of location of manufacture
• Capabilities available at a PoC can help mitigate production risks
• Entities should have clarity as to their responsibilities
• Leverage existing controls

## Potential 3DP Scenarios

<table>
<thead>
<tr>
<th>Scenario</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Minimal Risk 3DP by HCFP</td>
</tr>
</tbody>
</table>
| B | Device designed by manufacturer using validated process  
  • Turn-key system |
| C | Device designed by manufacturer using validated process  
  • Additional HCFP capability requirements |
| D | Manufacturer co-located at PoC |
| E | HCF becomes a manufacturer |
| F | Others? |
Scenario A - Concepts

Minimal risk in terms of patient safety and ability to print

<table>
<thead>
<tr>
<th>Risk Level</th>
<th>Who Uses Printers</th>
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</thead>
<tbody>
<tr>
<td>Minimal</td>
<td>HCFP</td>
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</table>

Scenario A — Concepts for Minimal Risk 3DP by HCFP at PoC

• Minimal risk of harm to patients

• Employ monitoring and risk mitigations strategies

• Leverage existing standards, certifications

• Not intended for implants, life-supporting / life-sustaining devices or devices that present a serious health risk to patients
Scenarios B and C – Concepts

• Device designed by Mfr to be printed by HCFP

• Cleared or approved based on validated 3DP process

• Workflow demonstrating that product specifications can be met when 3DP by end user

<table>
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<th>Scenario</th>
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</thead>
<tbody>
<tr>
<td>B – Automatic or self-contained post-processing steps (turn-key system)</td>
<td>HCFP</td>
</tr>
<tr>
<td>C – Additional HCFP capability requirements</td>
<td>HCFP</td>
</tr>
</tbody>
</table>

Scenario B – Concepts for Turn-Key 3DP Systems

- Device designed by manufacturer to be printed by the healthcare facility
- Uses a validated process that has been evaluated by FDA
- Post-processing steps are automatic or self-contained
- HCFP uses device consistent with cleared indications and manufacturer instructions for use
Scenario C – Concepts for 3DP Systems with Additional Processing

• More complex manufacturing and post-printing processes (e.g., machining, precision drilling, certain sterilization procedures, heat treatment)

• HCFP would have to have appropriately trained personnel and proper equipment

• Labeling, training, instructions for calibration, testing on-site, facilitate appropriate 3DP by HCFP
Scenarios D and E - Concepts

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<tr>
<td>D – Mfr or contract manufacturer co-located at PoC</td>
<td>Mfr and/or Contract</td>
</tr>
<tr>
<td>E – HCFP chooses to become a Mfr (develop, test, print)</td>
<td>HCFP</td>
</tr>
</tbody>
</table>
Scenario D – Concepts for Manufacturer Co-located at PoC

• HCFP doesn’t intend to setup and manage their own 3DP facility or devices are not minimal risk

• 3DP performed by traditional manufacturer, contract manufacturer, or other 3rd party using their equipment and personnel
Scenario E – Concepts for HCFP as a Traditional Manufacturer

- HCFP desires to design and control own 3DP operations and device is not minimal risk
- HCFP responsible for development/design, testing, and printing
- HCFP responsible for all regulatory requirements
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We would like to hear your **comments and questions** about these ideas. Please send them to the email address above.

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**www.fda.gov/3DPrinting**