ASME 3D Printing at Point of Care
Virtual Workshop
May 29, 2020

Executive Summary

ASME convened a workshop on May 29, 2020 culminating a series of meetings and webinars conducted to examine a risk-based, conceptual framework developed by the US Food and Drug Administration (FDA) for use at point-of-care manufacturing facilities. Various scenarios comprising the framework, outlined below, had been reviewed in detail in previous webinars.

Scenario	Description*
A	Minimal Risk 3DP by Healthcare Professional
B	Device Designed by Manufacturer Using Validated Process • Turnkey System
C	Device Designed by Manufacturer Using Validated Process • Additional Healthcare Professional Capability Requirements
D	Manufacturer Co-Located at Point of Care
E	Healthcare Facility Becomes a Manufacturer
F	Others?

Additional materials can be found at https://resources.asme.org/poc3dp-events

Members from diverse groups, including medical device manufacturers, point-of-care manufacturers, technology developers, and others participated in the half-day workshop, which included breakout sessions covering Scenario A - Minimal Risk 3D Printing by a Healthcare Professional; Accreditation; and COVID-19. The discussions focused on:

(1) identifying requirements and best practices for 3D printing at point of care
(2) accreditation of manufacturers as well as the type of training/credentialing needed for personnel
(3) quality management systems to assist in the determination of risk.

To ensure a robust dialogue, each breakout group included a mix of attendees from all stakeholder groups.

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Discussion highlights and breakout sessions are summarized below:

The FDA plans to develop a policy that will define the roles and responsibilities in the ecosystem for all the involved parties and ensure that 3D-printed devices used on patients are safe and effective. The policy is expected to address both clinical best practices and good manufacturing practices (GMP). For personnel certification, training requirements may vary according to the risk profile of the complexity of the printed product. Formal documentation of training is expected to be required, regardless of staff roles and type of training.

Scenario A is intended for products that most likely will not require a 510(k) review. It is expected that this scenario will encompass low-risk devices that can be printed at the point of care under the point of care's existing quality controls and quality systems accreditation.

Accreditation

The Accreditation breakout groups primarily focused on the following questions:

- What would a certification/accreditation program for PoC printing need to include?
- What documentation would be required?

For personnel certification, several attendees noted that they are currently utilizing the following existing documents and procedures:

- certifications and/or elements of existing ISO standards
- material certification in software certification awarded by vendors or other organizations
- documentation of training, record keeping, and auditing requirements

For facility certification, the following existing documents and procedures were noted:

- U.S. Good Manufacturing Practices (GMP) regulations
- documentation of QMS Process including verification and validation
- quality and risk determination

Participants also noted that for facility qualification, risk level and complexity of the device should be acknowledged when assessing the facility's capabilities. The facility's capabilities would impact the type of qualification required by personnel. Facilities may consider hiring a qualified risk assessment person who could help determine the level of classification of the device to ensure that the facility has the qualification required to print specific devices.

Additional considerations, such as physical distance of the printing facility from the POC facility and transportation and delivery of 3D-printed devices, also must be reviewed for facility certification.

Scenario A – Minimal Risk 3D Printing by a Healthcare Professional

Attendees agreed that applications that belong in Scenario A are as follows:

- Anatomical models
- COVID devices, PPE, Mask Attachments
- Assistive Tech, Assistive Devices
- Prosthetics (external)
- 3D Printed Face Shields
- 3D Printed Molds
- OP Table, Wheelchair Attachments
- 3D Cast, Splints, Braces, Orthotics

Cutting guides were discussed as a potential application for Scenario A, but attendees noted that these devices currently pose a significant risk, stressing that cutting guides are different from pre-surgical planning models. Medical device manufacturing companies may be creating these under Scenarios B and C, whereas anatomical model guides would fall under Scenario A.

Risk Determination

Risk assessment is wide ranging, scenario dependent, and POC dependent. Considerations include the intended use of the device and the characteristics of product that may impact patient safety. Examples of questions to consider when assessing risk include:

- Will the device be used in a patient consult or in a surgical theater?
- Will it have skin contact?
- Has a failure analysis been conducted determine the impact on the patient's health and safety? Should there be standardized protocol for handoffs to the surgical team and how should that communication be done?
- How should the product be labeled?
- How will the product be used?
- What acceptable alternatives are available if the device fails?
- What is the facility's capability to print the device? (That is, does it have the right materials, tools, equipment, personnel, etc.?)

Attendees also noted that standards are needed to prevent potentially conflicting guidelines from arising due to proliferation of proprietary rules. Variations among manufacturers' QC systems and procedures may also contribute to potential conflicts.

Point of Care Definition

The definition of "point of care" should answer the following questions, as raised by attendees:

- How physically near the point of care does an additive manufacturing facility need to be to be of clinical benefit? In the same region, city, borough, campus, or building? Specifically where patient care is taking place?
- What is the intent to market?
- Would considerations need to change if you are printing for another facility? Is that facility local or across state lines?
- What are the organizational models of the entities printing the devices? Examples follow:
    - Enterprise: single business entity with multiple campuses
    - Affiliated Institution: contracted services business service agreement between two separate institutions
    - External vendors co-located to provide support and ensure quality controls are in place and followed.

COVID-19

The development of foundational documentation or procedures to have in place for future crises would be useful so that POC facilities and manufacturers can ramp up much more quickly and prevent supply chain disruptions. One interesting comment that emerged was that for 3D printed materials, many different geometry files are available through, for example, the NIH repository. Attendees noted that additional parameters included in the repository, such as guidelines for efficient production and protocols for making secondary processes acceptable for delivery, would be especially useful for designers and manufacturers.

Understanding how state and local governments stepped in was discussed. Regional consortia of manufacturers, 3D printing exchanges, and technology developers working with hospitals were noted as sources to educate on regulations and device class categorizations in order to ramp up 3D printing as needed. In addition, local facilities may be able to fabricate devices to

In some countries, with 3D printing capabilities, there are no guidelines or protocols for onsite 3D printing. In emergency situations such as this, other countries look to the US and Europe for their standards and guidelines.

Blockchain was discussed as a potential technology in preventing future disruptions to the supply chain. local facilities building every bit of what's needed from design through fabrication.

Appendix A
Agenda

3D Printing at the Point of Care Concept Framework Workshop
May 29, 2020
11:00 am – 3:00 pm ET
Virtual Meeting

11:00 am- Noon	Review of discussion so far, focus on Scenario A; B&C points
	Guidelines for breakout discussions
Noon – 1:15 pm	Breakout discussions (Zoom rooms)
	1. Accreditation: Group 1
	2. Accreditation: Group 2
	3. Scenario A – What types of products fall under this Scenario? Group 1
	4. Scenario A – What types of products fall under this Scenario? Group 2
	5. COVID pandemic
1:15 pm – 1:30 pm	Break
1:30 pm – 2:15 pm	Report out from breakout discussions
2:15 pm – 2:45 pm	Discussion; questions
2:45 pm – 3:00 pm	Wrap-up and next steps

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Appendix B
Breakout Session Notes

Accreditation Breakout Session – Group 1

Certification/Accreditation

- What would a certification/accreditation program for PoC printing need to include?
  - Depends on Scenario (A may be class 1 medical devices- GMP (but not design controls)) B+C would need also need design controls as well as D+E
  - Would FDA be auditing? Who else may?
  - Anatomic models will also require segmentation certification- software certification.
  - Already use ACR machines
  - Depends on the risk level of these steps within the process.
  - Merging hospital practices and good manufacturing processes.
  - ISO 14971 is used for the medical device manufacturers and how is this translated to the hospital environment.
  - ISO 13485 may be applicable/ helpful to recognize some of those requirements
  - ISO 1700- CA in general may be applicable
  - SME Certifications- personnel certification can be a component
  - V&V approaches to certifying processes
  - Material certification
  - CFR 820 is relevant (QMS)
  - Personnel certification need: medical designs and certifications for segmentations; radiologists in segmentations; VA and RSNA are looking at this as well; Documentation of training.

Documentation

- What level of documentation (e.g., QSr, internal recordkeeping, verification/validation) and/or submitting new premarket submissions to FDA are needed when adding or changing CAD/CAM equipment (e.g., software, printer, post-processing) used for additively manufacturing medical devices under Scenarios B-E? What types of changes may be applicable to different types of documentation and/or submitting new premarket submissions?
  - Different validation systems needed per manufacturers' needs (different process validation) – is this different than what is done for existing processes/equipment in hospitals

- Record keeping needed for both machine qualification and process qualification (e.g. build envelope). Different elements of process that need to be considered for requirements- essential variables vs. nonessential.
- Need to have the process clearly defined and documented and documentation on that validation.
- Risk needs to be considered when changing processes (look at guidance documents for this). Risk assessment is what determines essential vs non-essential steps/factors. This will be related back to the various scenarios/ device classifications. This is also affected by the complexity of the device.
- This should be a part of your QMS- assessing the risk through the phases of production (should be the same for 1,2,3 classes of devices). Need a QMS in place for POC facilities. CLIA - established quality standards for non-research laboratories performing diagnostic testing on human specimens. Based on the complexity of the testing method, the FDA classifies all laboratory tests into three categories: waived, moderate, and high complexity. CLIA requires laboratories performing these tests to be certified and bases regulations on the complexity of testing performed. The higher the complexity the more encompassing the regulation. CLIA quality regulations include requirements for: Personnel and Responsibilities, Proficiency Testing, Pre-Analytic, Analytic, Post-Analytic, QC/QA and Facility Administration. CLIA may be a good model for accreditation and starting point. Provides a good framework- involves the complexity classifications put by the FDA. One thought- Is this excessive for a POC to implement? May need to be divided by the different scenarios. (POC labs will not be able to meet this). There are components that may be needed. "A minimum level of quality expected for all scenarios". The extent of the QS requirements will all go back to risk.
- Should E be treated differently than B+C? What levels of consistency needs to be made (decision- should be treated the same) Scenario E needs to be considered further.
- AB+C- what minimum documentation needs to be required? Device history record may need to be a large part of this? Traceability of documentation is often brought all the way to the patient file. This is the translation point to the EHR. Not uploaded to medical record but can be traced back.
- Scenario A documentation- risk assessment training and risk mitigation for all those involved (can be tied to SOPs) to avoid variations of process.
- Premarket submission will need significant further testing (additional)
- Cutting guides are the biggest risk at this time done in the hospitals right now- they are different than pre-surgical planning models. Medical device manufacturing companies may be creating these under B+C.
- Need a definition of what a guide is (from the FDA)- CPT Codes for reimbursements may be a good reference. As soon as a model is in hard it can affect approach to surgery (despite

original intent not to be a guide). Scenario A may be only applicable to educational models. As soon as you get past that it should be under other scenarios.

Accreditation Breakout Session — Group 2

SUMMARY

- Facility qualification
  - Different levels similar to what is already done for hospital labs (CLIA)
  - Capability levels not specifically tied to scenarios
    - You could have an application within scenario A that requires a higher level of capabilities
  - Would include things like an appropriate QMS
  - Depending on the capability level, a different set of personnel qualification may be needed
- Personnel qualification
  - Varies depending on level of facility capabilities needed
  - Could use combination of existing certifications and qualifiers
  - General AM/3DP, Software and machine operator levels from vendors
  - Documentation of training

NOTES

  - Facility qualification

- What aspects of regulatory things might a hospital need?
- Risk accreditation for an individual, to determine at hospital to decide which scenario applies, fits in Scenario A
- Printers being used—people (person) knowledgeable/qualified on the machines they are using
- Machine should be qualified & validated to certain parameters—different requirements based on risk assessment (scenario A, B, etc.)
  - Comparing input to output—make sure it turns out the way you intended
  - Joint commission could add this in as a module; QMS check for your printer—similar to other programs—for scenario A—qualification schedule eg, every X print or time or check every part or change parameters or change material or use recycled material--needs to be qualified as part of the QMS

        - Include preventive maintenance? At least some machine builders have preventive maintenance schedules; include triggers that would be covered in training
    - Production part approval process; set of questions, documentation
    - Printer itself is generally not a device; making qualification of your machine important
    - Manufacturing facilities are subject to inspection whether machines, tools are cleared as devices
    - Need GMP, QMS light
    - Accuracy needed depends on the risk level
        - using a model to size or develop tools or surgical guides requires a higher accuracy than a model used for planning
        - different capabilities needed for patient-specific guides, implants, tissues
        - what exists within joint commission for tissue labs?
    - Do all of this to minimize burden on hospital; capability analysis similar to what the VA is looking to do
    - Best practices guide on capability analysis and what that analysis leads you to—Level, low to high need
        - May be possible to have a higher facility need for different applications; all within scenario A
        - Labs CLIA 1988—categorizing laboratories based on their capability; receive certification for facility that requires both facility and personnel qualification
        - Turn-key systems: each element of the system, there should be a standard process to evaluate for that application; demonstrate repeatability, plan for keeping the printer and system qualified
    - Personnel Qualification
- Categories:
    - segmentation,
    - design
    - running printers
    - no individual accreditation at device manufacturers
- General AM certifications exist; medical may need some qualification for segmentation & other

- Inspection certification? Higher the capability of the facility, the higher the qualification needed; even at low level, you need to have at least the person with the caliper; all measurements in radiology are calibrated
- General anatomy qualification? Is there anything in radiology that covers this? Work with surgeons & radiologists for expertise in anatomy; could reduce time to trust for an engineer to have some level of anatomy qualification
- Do software companies provide certificates or certification for users? Different levels? Similar to SolidWorks levels—both design and segmentation certificates; slicer software—document training & proficiency; use as much existing ass possible
- There are a series of existing certifications that could be used for a total requirement—depending on facility capability level again

Scenario A: Minimal Risk 3DP by Healthcare Professional Breakout Session – Group 1

Risk Determination

What considerations should be taken into account when the PoC is making a minimal risk determination?

- Thought process when determining if something is in Scenario A, looking for feedback about what would need to be considered to determine the Framework.

1) What is the Intended Use?

  - How is it being used? – patient consult vs. in the surgery room,
  - How does it fit in patient case story?
  - Does it confirm the diagnosis? Or will it change the course of treatment?
  - Foreseeable misuse of product
    - Identification of limitations of models via handoff discussion to team or surgeon.
    - Standardized protocol for handoffs of model communication – labeling.
  - Evaluation of Hazardous situations through use of device.

2) Characteristics of Product that Impact Patient Safety

  - At what level does it come into contact with the patient?
  - No contact only vs skin contact with user of device and/or patient?
    - Mold vs. Product e.g. 3D printed mold/casting e.g. Maxillofacial prosthetics
    - Marking Guides – what is level of risk if alignment is off?

- Failure Mode analysis – what are the consequences of failure to patient and health care provider
- Long term risk to a patient

What considerations should be considered when the PoC is making a minimal risk determination?

3) Who is using the product? One off usage vs. Reusable / multiple patient use

- Reuse across patients vs. reuse by same patient
    - Fatigue, mechanical properties, sterilization, reprocessing, biocompatibility, etc.
- Incomplete discussion - Would the community be interested in the option to perform a study for risk mitigation on reusable items to demonstrate if something is minimal risk - e.g. tool grip for surgeon's hand
- Are reusable products part of Scenario A or if they require more validation which would exempt is from A

4) What is the alternative?

- If this goes wrong what is available?
- Is there an off the shelf product available?
- Risk of not providing the product.

5) Can we print it?

- Produced using a specific technology – does PoC have that technology
- Materials
- Tools
- Staff Expertise
- Sterilization – Validation
- Process controls in place
- Accreditation requirements met
- Volume and number of devices being printed

Types of devices

- Marking Guides
- Mold – manufacturing aid – cement spacer
- Models - regulated software design
- Surgical Tools / Guides

- Implants – no load bearing implants? - Not Scenario A
- Prosthetics – over engineered at present
- Dental guards
- Nasal Swabs –performance concerns
- Assistive therapy devices- tablet over hospital bed -

Definition of POC

- How physically near the point of care does an AM facility need to be to be of clinical benefit (region, city, borough, campus, building)
  - Would considerations need to change if you are printing for another facility?
  - Enterprise – single business entity with multiple campuses
    - Similar quality processes or separate controls – similar controls but perhaps different technology.
  - Affiliated institution - contracted services business service agreement between 2 institutions
    - Similar controls – difference in risk?
    - Device failure reporting
    - Design Control - Documentation consistency
  - Unrelated institution – Scenario E

Scenario A: Minimal Risk 3DP by Healthcare Professional Breakout Session – Group 2

Characterizing Scenario A Discussion

What applications belong in scenario A:

- Anatomical models
- COVID devices, PPE, Mask Attachments
- Assistive Tech, Assistive Devices
- Prosthetics (external)
- 3D Printed Face Shields
- 3D Printed Molds
- OP Table, Wheelchair Attachments
- 3D Cast, Splints, Braces, Orthotics
- Cutting Guides (anatomical guides AMA ref.)

Risk Determination

What considerations should be taken into account when the POC is making a minimal risk determination?

- Risk assessment is wide ranging, scenario, and POC dependent
- Many non-experienced professionals are attempting manufacturing
- Medical device manufacturers have knowledge
  - But their QC systems also vary from mfg. to mfg.
  - Proprietary knowledge
- Patient advocacy groups
- Standards, guidelines need to stop proprietary rules, QC systems/procedures from proliferation

Definition of POC

- How physically near the point of care does an AM facility need to be to be of clinical benefit (region, city, borough, campus, building)
- Literally where patient care is taking place
- External vendors & hospital should have immersive relationship
  - Vendor or hospital staff co-located to provide support and ensure QC
- Intent-to-Market (local vs across- state line hospital
  - This is a grey area that needs to be carefully considered

COVID-19 Breakout Session

- Practice of medicine – BUT – when spreading out over networks, it gets muddy
- PPE – is it a device

Quality focuses on final product

COVID – focus on function and material

Performance of materials during fabrication and use

Printing something in hospital: clear boundaries between manufacturer and clinical care

Surgical – patient-specific

Swabs are more corporate manufacturer – from a compliance perspective – physicians push back

- System of production for authenticated materials, methods approved for fabricating the device – GMP
- Go through V&V for testing
- No turnkey system for these types of devices (trade secret)
- 3M was making masks – did research and innovated – and didn't meet the need. Nationalization of priorities – proprietary information was not shared far enough in advance

- Need fabrication ecosystem in place before the crisis – goes to lowest bidder
- In lab or hospital – does GMP need to be involved?
- Requirements for GMP relate to risk
- What kind of submission/approach we can use – central point –
- Class 2 – need GMP in place
- Pre-EUA

Nuances

- GMP exempt – extra layer
- Design controls

After the pandemic passes – what will happen to the products that were approved by EUA? After the emergency is rescinded, those devices can no longer be marketed. What about hospitals that already purchased it? Ability to use it does not go away

- Traditional mfg for mass production

If POC had 3D printing, it showed the benefit of having the capability onsite in an emergency. Can reverse engineer. With a toolbox of files, these facilities can provide support.

Find a way to have backup of files for 3D printed parts of machines

For medical device companies, they were required to be flexible with customers – fewer elective surgeries

NIH repository – take it a step further to include a protocol for getting those acceptable for delivery

- "There's a lot of different geometry, files that are available – a lot with different requirements to be put into use – approved primary file – then apply a standard for finishing processing"

COVID-19 Local Governments

Regional level – Ohio governor – individual governments

Formlabs – 3D printing consortium for manufacturers

NIH-VA print exchange

Regulatory depth and knowledge not high in industry and clinical world

What do you need when printing at the hospital?

- Panama – government assigned tasks for humidifiers, respirators, but there were no guidelines, protocols – They look to other countries with regulations and standards –

Need to share with countries with no protocols in place for emergency situations

Blockchain

- Clear boundaries between manufacturer and clinical care

Surgical – patient-specific