

3D Printing Medical Devices at Point of Care Scenario A: Minimal Risk 3D Printing by a Healthcare Professional

Highlights from the ASME January 21, 2020 Webinar

In defining minimal risk, panelists noted that the **intended use** of the printed device plays a major role in evaluating risk. Specific uses include:

- visualization
- planning and guiding surgery
- decision-making for treatment
- patient education
- training of healthcare professionals

Healthcare professionals at the point of care may be able to **rely on precedent**, such as **safety risk analyses** used by manufacturers of traditional medical devices. Those manufacturers quantitatively analyze risk, look for ways to mitigate the risk, re-evaluate the process, and then revise the process as necessary.

Additional precedents noted by panelists included

- **FDA's Software as a Medical Device (SaMD)** framework (<https://www.fda.gov/media/100714/download>)
- ISO 13485

Panelists also discussed managing quality and mitigating risk for healthcare institutions that span multiple sites and states. One speaker noted that a centralized program for all sites was necessary to quantify and control risk, develop a quality management system (QMS), and create shared standard operating procedures (SOPs) across all sites.

Besides hospital systems, **physicians' and dentists' offices** also were noted as potential locations where devices could be 3D printed. How do the various locations affect risk profile? One proposed solution is to **develop a rubric** that accounts for location, competencies of the personnel at the location, and the product to be printed.

Regarding **training and competency requirements** of POC personnel, panelists agreed that training varies according to risk profile and complexity of the printed product. Formal documentation of training must be archived in a personnel folder, with a notation of specific competencies--such as ability to read segmented data or design a product for intended use.

And a "trained healthcare professional" should encompass **all involved in the designing and printing** of the device: radiologists, surgeons, occupational therapists, orthotists, and prosthetists, among others. Indeed, because user error even in a validated system can increase patient risk, panelists agreed that personnel training should be a requirement.

In **defining the scope of 3D printed devices**, participants noted that a "3D printed device" comprises the following:

- Software
- Hardware
- Raw materials
- Controls
- Maintenance plan
- 3D-printed product

In **establishing scope** of Scenario A, there appeared to be consensus that the following applications should be **excluded**:

- patient-contacting materials, including all implants
- products requiring sterilization
- products that affect diagnoses
- products used for surgical planning

One panelist referenced the FDA's SaMD guidance, noting, "If it goes into the surgical suite, it's not minimal risk."

Variables to be noted when **assessing risk and quality** include:

- How much control does the manufacturer have over the material, process, and final product? How much control does the user have over these same variables? Whether the hardware/software/materials already have clearance as a device through the FDA can be a significant risk-mitigating factor.
- Does the facility have the capability to print the same item repeatedly and reliably? Some panelists posited that an off-the-shelf product may pose greater risk. "Printing 1,000 parts for 1,000 patients, as opposed to a single part for a single patient, may ironically mean more risk," with another panelist adding, "Those parts may be used on patients you haven't seen or met, which increases risk."

Throughout the webinar, panelists recommended creating **certification programs** as a mechanism to help mitigate risk, reduce the likelihood of human error, and ensure quality systems. By certifying personnel as well as processes and equipment, POC facilities may be able to reduce the number of required inspections and forego formal premarket review for each product.