3D Printing Medical Devices at Point of Care

Scenario B—Device Designed by Manufacturer Using Validated Process: Turn-Key System

Scenario C—Device Designed by Manufacturer Using Validated Process: Additional HCFP Capability Requirements

Highlights from the ASME February 20, 2020 Webinar

The information presented is for discussion purposes only, is not guidance, and is not intended to implement policy changes.

What Is the Working Definition of "Turnkey Package"

- A turnkey package includes software, hardware, and process parameters including material requirements.
- The manufacturer would receive clearance/approval by the FDA for a specific product to be made using the turnkey system at point of care. The validation of the turnkey system and human factors associated with printing at point of care would be assessed during the FDA review.

One panelist noted that we may be able to leverage an approach already used in the dental space, where a submission for a turnkey package includes software, hardware, and process parameters for clinicians who need to make a product in a specific set of design limitations. A traditional manufacturer could request clearance from the FDA for a product. The product is tested by manufacturer to ensure that end user can produce a product that meets appropriate standards. Only the product is regulated.

What would a turnkey system/validated 3D printing system need to include to make this option viable and attractive for both industry and clinicians?

Two criteria arose during the discussion:

- **Patient matching:** the industry wants to provide solutions that are economically viable and can be tailored to individual patients. Future considerations should account for use of AI in design.
- **Clinical usability:** products need to be simple and robust. The process must be easy to use.

Panelists also agreed that training and certification is an integral part of a turnkey system. The manufacturer of the printer must provide training and issue a certificate to limited personnel who would be involved in the manufacturing of the medical device at the point of care.

What kind of training at POC would be required when implementing a turnkey system? Who would require training?

One panelist noted that a precedent exists for lower-risk devices such as anatomical models. In this case, training involves facilitating a user manual on setup, operating systems, and steps to run software and produce a model for diagnostic applications. Additional training and certification will be required for higher risk devices printed at POC.

Oversight is another consideration for training. **One issue to be resolved is whether FDA should regulate the POC facility or the manufacturer.** Given that Scenario B is more turnkey, perhaps a manufacturing certificate would suffice. In Scenario C, where the facility would have more freedom and flexibility, an accreditation body may be needed to certify training.

What is the risk profile of a device falling into these scenarios? Would any types of devices be excluded?

The manufacturer must determine if it can properly validate and control its process to make the device at POC. It also may be attractive to use low-risk devices for situations when the POC facility would not want to conduct the risk assessment required of Scenario A. The industry will look to clinicians and hospitals for guidance, as exclusions are often based on usability--not on risk and whether one can control process at POC facilities.

How would liability be assigned?

Hospitals and healthcare facilities are moving from a role of buyers of end products to buyers of tools to make a product. The POC facility is therefore taking increased liability based their responsibility for using tool correctly even though that tool is FDA-approved. The onus for liability is on the hospital's quality system.

The burden does remain, however, on the manufacturers to ensure that they are selling a printer to a facility that is capable of using it.

What are the criteria for establishing reliability and quality of the product?

The FDA would not expect product reliability or quality to change based on the place of manufacture. The product must meet any applicable standards.

Both the medical device manufacturer and the POC facility would be required to maintain a documented safety and risk analysis process. The process musts demonstrate how the device is produced and used, with documentation of testing and reliability required to show that a standard has been met. An accreditation board could review and provide feedback.

Select Audience Questions

The term "complexity" has been used, and I would like to clarify what is meant by this. Are we concerned with the complexity of end product design or of the process to manufacture?

"Complexity," in this discussion, is used in terms of the device being manufactured. Complexity could refer to design, a segmentation in CAD, or just in terms of the manufacture of the product itself.

With regard to 42 CFR 493.5, complexity is related to the laboratory process. If it involves sophisticated machinery and requires operator with advanced training, then the product is deemed more complex.

If a printer and the product it produces is "plug-and-play" with no flexibility, and the end user is required to buy material from manufacturer, this would be considered low complexity and waived by CLIA.

We have been talking about hospital-based printing, but would doctors' or dentists' offices fall within this scope?

Yes, all POC facilities, including doctors' and dentists' offices would fall within this scope. There will be different levels of risk and risk mitigation based on location, the product being manufactured, and who is conducting the assessment. Requirements may differ among locations. Leveraging third-party accreditation could be a valid mitigation strategy. It would be the manufacturer's responsibility to determine who can use their product at POC.

What happens when same printer that makes both high- and low-risk components

FDA is envisioning that validated systems could be used across multiple products. End users would need to follow indications for use.

If system has a fully validated design by manufacturer, an uncleared design might be prohibited. If a workaround is found with no cleared features, an accrediting body or FDA would need to monitor if the printer is being used for intended use.

What, if any, information should be disclosed to patient on how and where device is manufactured and tested?

Use of a hospital printed device would be part of the informed consent process, which typically discusses risk, benefits, and alternatives. The level of discussion would be dictated by the nature of risk and the severity of risk; nevertheless, this should be part of the informed consent process.

Depending on level or class of product in a system, a device could be subject to labeling requirements that would be available from the Freedom of Information Act. In that case, the location of the manufacturer would be available.

What level of material authentication must be provided to the FDA that performance must be met? What do sources of materials suppliers need to provide?

One panelist noted that manufacturers should supply an information sheet on their material, with evidence that they have tested it, followed instructions for use, and have performed mechanical and biocompatibility testing.

Another panelist added that some of the certifications could come from manufacturer; however, additional testing may be required at the end user's facility and a third-party lab. Biocompatibility and sterility are key concerns.

What are the thoughts with respect to quality systems regulations applicable to POC? Would POC keep track of complaints or would the manufacturer?

The onus for quality systems is on the printer manufacturers, as they have regulatory clearance. They would need to field and report the complaints as reportable events, if applicable. "Quality system" refers to requirements for operating their systems in the POC facility. Another panelist noted that, in theory, this approach seems reasonable and ideal, but in practice, it may be difficult to enforce. Agreements would need to be established between the manufacturer and POC. The POC is responsible for contacting the manufacturer if any problems arise and they are unable to determine the source of the problem.

Organizations and Publications Referenced on the Webinar

- **CLIA: Clinical Laboratory Improvement Amendment of 1988:** https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA
- **42 CFR 493.5:** Category of Tests by Complexity
- **CFR 429.71:** Maintenance of Records