

Guidance Regarding New Respirator PPE Development in a Public Health Emergency

There are growing efforts in 3D printing personal protective equipment (PPE) for the health care community during this Public Health Emergency. The enthusiasm and creativity from our communities is truly inspiring. If you are involved in 'Research and Development' design and printing PPE prototypes, please read the following for important information on constraints for certain Respirator PPE designs and corresponding Food and Drug Administration (FDA) guidance.

Q: Can EHS help me validate a 3D printed filtering face-piece respirator design?

A: No, EHS is not able to validate the performance criteria of new 3D-printed FFRs. The National Institute for Occupational Safety and Health (NIOSH) is the only OSHA-recognized body that can legally evaluate and validate performance of FFRs for non-medical use. Additionally, all manufacturing, distribution and use of medical devices, including FFRs is regulated by the Food and Drug Administration (FDA). During this Public Health Emergency, federal guidance is changing rapidly. The FDA's most recent guidance on this topic is here: [FDA Guidance on Enforcement Policy for Facemasks and Respirators](#)

Q: Can EHS help me with fit testing our 3D printed filtering face-piece respirators (FFR)?

A: A fit test does not ensure criteria regarding loading, inhalation, and exhalation resistance, or efficiency are met; it only validates a respirator fit. A qualitative respirator fit test determines if a subject can taste an aerosolized challenge agent (typically Bitrex or Saccharine) while wearing a respirator. Passing a fit test simply indicates that the respirator is the correct size and only draws air through the filter rather than leaking unfiltered air through a gap in the seal and the users face. At this time, EHS can only perform NIOSH-approved fit test procedures on 3D-printed FFRs for Academic 'Research and Development' on a case-by-case basis. This is meant for academic prototyping purposes only, and CAN NOT certify or approve occupational use. EHS may request that makers, contact the FDA (see next Question) before EHS can offer a qualitative fit test. At this time we are prioritizing work with UVA researchers. EHS can also provide external resources on ways to achieve an optimal respirator fit; please see 3M's website here: [3M Fit Testing Process](#)

Q: What else is critical to know if I am 3D printing filtering face-piece respirators (FFR)?

The FDA may issue Emergency Use Authorization (EUA) for non-NIOSH approved FFR use in healthcare environments during the Public Health Emergency. EHS will consider fit testing the FFR for UVA researchers/makers who have contacted the FDA. The FDA indicates an EUA, for any FFR's in a healthcare facility used during this Public Health Emergency, is necessary per FDA's most recent guidance on this topic: [FDA Guidance on Enforcement Policy for Facemasks and Respirators](#)

Q: Can 3D printing be used to make gowns, masks, respirators, and other types of personal protective equipment (PPE)?

A. PPE includes protective clothing, gowns, gloves, face shields, goggles, face masks, and respirators or other equipment designed to protect the wearer from injury or the spread of infection or illness. While it is possible to use 3D printing to make certain PPE, there are technical challenges in regards to performance that have to be overcome to provide beneficial protection for our healthcare providers. Simply put, Personal Protective Equipment needs to perform well enough to protect. There are industry consensus standards for the performance of the range of protective equipment that must be engineered into the design to provide a benefit to the user.

For example, 3D-printed PPE may provide a physical barrier, but the materials used in most designs available online for 3D-printed PPE are unlikely to provide the same fluid barrier equivalency and air filtration efficiency as FDA-approved surgical masks and respirators. The CDC emphasizes following recommendations for how to [optimize the supply of face masks](#).

Q. Can I use PPE made by 3D printing?

A. 3D-printed PPE can be used to provide a physical barrier to the environment. However, materials used in most 3D-printed designs available online are unlikely to provide the same fluid barrier equivalency and air filtration efficiency as FDA-approved surgical masks and respirators cleared surgical masks and N95 respirators. The CDC has recommendations for how to [optimize the supply of face masks](#).

Q. Can entire medical devices be 3D printed?

A. While the FDA understands that 3D printing may occur to provide wider availability of devices during the COVID-19 public health emergency, some devices are more amenable to 3D printing than others. The FDA intends to work collaboratively with these manufacturers through its EUA process. Entities should email COVIDManufacturing@fda.hhs.gov for more information.

Q. How is the FDA working to mitigate PPE and component, part, and accessory shortages?

A. We recognize that when conventional products are unavailable, some entities are considering printing or purchasing 3D-printed devices. The FDA is working closely with government, industry, and health care facility stakeholders on this and on the broader public health emergency. The FDA recently authorized an Emergency Use Authorization (EUA) for ventilators, ventilator tubing connectors, and ventilator accessories, which could include items such as 3D-printed tubing connectors for multiplexing ventilator use. The FDA also is collaborating with the Department of Veterans Affairs (VA) Innovation Ecosystem, America Makes Public-Private Partnership, and the National Institutes of Health (NIH) 3D Print Exchange, a resource from the National Institute of Allergy and Infectious Diseases at the NIH. However these designs have not been evaluated by the FDA or NIOSH for the performance of any of these devices.

See the [FDA](#) website for more information.