QUICK GUIDE TO HOW VA IS APPROACHING FACE MASKS AND RESPIRATOR SUBMISSIONS TO THE COVID-19 COLLECTION ON THE NIH 3D PRINT EXCHANGE

GENERAL USE FACE MASKS

General use face masks* protect the wearer from physically contaminating their mucous membranes (mouth and nose) with virus on their hands, and additionally decrease the risk of asymptomatic COVID+ wearers of the mask unintentionally transmitting the virus. These are not intended for use by health care professionals in a health care setting. These may or may not meet fluid barrier or filtration efficiency levels. * Of note: Recent CDC guidance recommends the use of "cloth face coverings in a public setting where other social distancing measures are difficult to maintain (e.g., grocery stores and pharmacies) especially in areas of significant community-based transmission." General use face masks stamped with "Designs optimized for community use" could potentially fit into this guidance category.

DESIGNS OPTIMIZED FOR COMMUNITY USE

CAN BE 3D PRINTED BY ANYONE

*DOES NOT REQUIRE GMP CERTIFIED MANUFACTURING FACILITY

DOES NOT REQUIRE AN FDA EMERGENCY USE AUTHORIZATION

SURGICAL FACE MASKS

Surgical face masks are specifically designed for a health care setting, and they carry the important distinction of being able to provide a physical barrier from fluids and particulate materials. They protect the wearer from large droplets, splashes, or sprays of bodily or other hazardous fluids. They also protect a patient from the wearer's respiratory emissions.

These do not protect against inhaling smaller airborne particles, such as those potentially transmitted by coughs, sneezes, or certain medical procedures. These are usually loose-fitting around the edges of the mask and do not require a tight seal.

DESIGNS REVIEWED FOR CLINICAL USE

MUST BE CREATED IN A GOOD MANUFACTURING PRACTICES CERTIFIED FACILITY

DOES NOT REQUIRE AN FDA EMERGENCY USE AUTHORIZATION

N95 RESPIRATORS

N95 Respirators offer our front line health care providers all the protections of surgical face masks but additionally offer protection from the inward leakage of small aerosolized particles into the mask at a higher efficiency level. These require a tight seal, so there is minimal leakage of air around the edges of the mask when the wearer breathes in. The CDC does not recommend that the general public wear N95 respirators .

What is the efficiency level of N95 respirators? Per 42 CFR 84.181 – N95 respirators have 95% filter efficiency (block 95% of very small 0.3 micron particles).

REQUIRES SPECIFIC EMERGENCY USE AUTHORIZATION FOR FDA

MUST BE CREATED IN A GOOD MANUFACTURING PRACTICES CERTIFIED FACILITY

FREQUENTLY ASKED QUESTIONS (FAQ):

What distinguishes a general use face mask from a surgical face mask on the NIH 3D Print Exchange? This comes down to the tests that are required for a mask to be labeled a surgical face mask. Most mask designs have two important components: the main body of the mask, which can be 3D printed or made with other hard non-porous materials, and the filter media. The materials used for the filter media and for the main body of the mask both need to be tested. It is the scrutiny at which these components are tested that determines which type of face mask a design can be used for.

What is the evaluation process for general use face mask proposals?

1. Is there appropriate documentation to describe how the device should (and should not) be used?
2. 3D printability test: is there enough information provided for someone to understand the type(s) of 3D printer, the printer settings, and the appropriate materials to use? If non-3D printed parts are required, is there a clear list of materials that the maker/manufacturer needs to buy?
3. Assembly test: Is there enough information provided for someone to properly assemble all of the components? (Think Ikea-style diagrams, etc.)
4. Durability testing: Will the mask hold up to repeated use, such as putting it on and taking it off multiple times, without breaking or falling apart?
5. Adequate airflow assessment: Can the wearer breath comfortably when wearing the mask? Specifically, can the wearer walk for 2 minutes with the mask on, and not feel like it is hard to breath?
6. Sizing/fit evaluation: Does the mask conform reasonably well to an average user's face? Are there large gaps or poor sizing over facial features such as the nose bridge? Is the fit good enough that the majority of air being breathed passes through the filter component when used?

What is the evaluation process for surgical mask proposals? In addition to the criteria outlined above, additional tests used for evaluating surgical mask design proposals include:

1. Fluid resistance testing: This test evaluates the liquid barrier protection provided by the face mask and is conducted with a protocol equivalent to the ASTM F1862 standard. Bottom line: Does it stop blood and other bodily fluids from passing through the mask?
2. Flammability resistance evaluation: The device must pass Class I or Class II flammability requirement per 16 CFR 1610, or specific labeling must be included to instruct the user to avoid high heat and open flame while using this device.
3. Adequate air exchange testing: The device is tested to measure the air flow it provides to the user by following the protocol outlined in the MIL-M-36945C 4.4.1.1.1 standard or by testing the device during simulated clinical scenarios where multiple users complete a 2 minute round of CPR while wearing the mask. Bottom line: you don't want to become hypoxic while wearing your mask.
4. Bacterial filtration efficiency: How well can the mask stop aerosolized bacteria? ASTM F2101.
5. Sub-micron particulate filtration – ASTM F2299.

What is needed for a N95 design proposals? Respirator (N95 type) devices offer the highest level of protection to the user, and because of this, require the highest level of performance testing and evaluation of the three types of face masks. A proposal for supplemental respirator device requires a formal submission of an Emergency Use Authorization (EUA) to the FDA. More information about what is required can be found in the Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency guidance from the FDA. Some of the performance testing requirements for these face masks which are needed for the EUA submission include NIOSH APPROVAL OF RESPIRATORY PROTECTIVE DEVICES- 42 CFR 84 and OSHA Respirator fit testing - 29 CFR 1910.134 Appendix A.

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