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

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.
5. Sub-micron particulate filtration – ASTM F2299.

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:

2. 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.
3. 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?
4. Adequate airflow assessment: Can the wearer breathe 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?
5. Assembly test: Is there enough information provided for someone to properly assemble all of the components? (Think Ikea-style diagrams, etc.)
6. 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?
7. Stability testing: How do the mask perform when subjected to wear and tear?
8. Design suitability: Is there a clear list of materials that the maker/manufacturer needs to buy?

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.

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).