Standards and Guidance for Developing Prototype PPE Devices

UVA Specific Guidance

The University does not want anyone to mistakenly think it is profiting off PPE devices developed by the University community. As such, developed items may not bear UVA branding logos, such as athletic marks (Block V, V-sabre) or special marks (Rotunda), or have a name associated with a UVA brand. While items may not have logos, they can incorporate UVA colors.

Personal Protective Equipment (PPE)	**Design Guidance**
Face Shields	• Covers the entire front (that extends to the chin or below) and sides of the face. • Meets FDA's Emergency Use Authorization scope and conditions to include: ○ The face shield does not contain any materials that will cause flammability, or the product meets Class I or Class II flammability requirement per 16 CFR 1610 • Latex free materials preferred. Include labeling if latex use is unavoidable. • Band material does not easily slip when worn.
Medical (Procedure/Surgical) Masks	• ASTM F2100 Level 1 minimum barrier protection with test method ASTM F1862/F1862M (Synthetic Blood); ASTM F2101 (Bacterial Filtration Efficiency), and ASTM F2299 (Particulate Filtration Efficiency) • Class I or Class II, Normal flammability based on 16 CFR Part 1610. • Consider ear hook style if for re-use. • Latex free materials preferred. Include labeling if latex use is unavoidable.
Respirators and Filters	• ASTM F3387: Standard for Respiratory Protection • Filtration standards listed above for Masks • 42 CFR Part 84, Subpart K (Particulate filter efficiency) • NIOSH Particulate filter efficiency STP for either N95 or N100 efficiency (95% and 99.97% of airborne particle efficiency) • 42 CFR Part 84, Subpart H (Inhalation and exhalation leakage) • NIOSH Exhalation Valve Leakage STP • NIOSH Inhalation Valve Leakage STP • NIOSH exhalation resistance STP • Latex free materials preferred. Include labeling if latex use is unavoidable.
Powered Air-Purifying Respirators (PAPRS)	• NIOSH STP for Air Flow Determination • NIOSH STP for Particulate Penetration

The Food and Drug Administration (FDA)

The FDA has issued guidance to help expand availability of certain PPE during the COVID-19 public health emergency.

FDA Guidance on Enforcement Policy for Facemasks and Respirators provides information on face masks, face shields, and N95 Respirators intended for healthcare environments.

FDA Emergency Use Authorization for Face Shields details the scope and conditions for emergency use of newly developed face shields by health care personnel.

ASTM Standards

ASTM develops international standard testing methods. Access to ASTM standards is available through UVA's Alderman Library:

https://compass.astm.org/CUSTOMERS/index.html and search for applicable standard (listed below).

Medical Masks

- ASTM F1862/F1862: Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)
- ASTM F2100: Standard Specification for Performance of Materials Used in Medical Face Masks
- ASTM F2101 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials.
- ASTM F2299 Standard Test Method for Determining the Initial Efficiency of Materials used in Face Masks to Penetration by Particulates Using Latex Spheres

Respirators

- ASTM F3387: Standard for Respiratory Protection
- Filtration standards listed under Masks

NIOSH

Standard Respirator Testing (STP) procedures identified in the table above can be found on the following NIOSH website: https://www.cdc.gov/niosh/npptl/stps/respirator_testing.html

Design Guidance for Respirators 42 CFR Part 84

Consumer Product Safety Commission

CPSC 16 CFR Part 1610 Standard for the Flammability of Clothing Textiles: https://www.cpsc.gov/s3fs-public/pdfs/blk_pdf_textflamm.pdf