Secretary of Public Safety and Homeland Security

Commonwealth of Virginia COVID-19 PPE Retooling Playbook

Information current as of April 2020 unless otherwise noted
This document is meant to provide a summarized fact base on potential immediate supply strategies, including manufacturer retooling, for increasing critically needed PPE across the Commonwealth of Virginia to address the COVID-19 crisis. **This document is a tool; it is NOT a commitment that the Commonwealth will purchase PPE offers of assistance.** This document does not limit the government’s policy on where and how to purchase PPE or medical devices in response to COVID-19.

**Given the urgency of the situation, this document seeks to rapidly synthesize information in a timeline that would not be appropriate in other circumstances.**

The purpose of this playbook is to provide Virginia manufacturers with a guide to producing PPE for COVID-19

### Objectives

<table>
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<tr>
<th>Playbook contents</th>
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<tr>
<td>Share critical Personal Protective Equipment (PPE) needs with Virginia manufacturers</td>
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<tr>
<td>Description of PPE product types required by Virginia healthcare workers, first responders, public workers, and general population</td>
</tr>
<tr>
<td>Share need-to-know information on regulations and requirements for the production and distribution of PPE</td>
</tr>
<tr>
<td>High-level perspective on industries that are well-suited to produce certain types of PPE</td>
</tr>
<tr>
<td>Assist Virginia manufacturers with navigating the path to producing PPE in support of the Commonwealth of Virginia</td>
</tr>
<tr>
<td>Synthesis of the FDA Enforcement Policy for PPE during COVID-19 and implications for manufacturers</td>
</tr>
<tr>
<td>Process maps and example courses of action for non-medical manufacturers to retool for PPE production</td>
</tr>
<tr>
<td>Product information sheets for each type of PPE</td>
</tr>
<tr>
<td>Additional resources and assistance for each step of retooling</td>
</tr>
</tbody>
</table>
Commonwealth of Virginia COVID-19 PPE Retooling Playbook contents

1. Descriptions of critical PPE types in demand by the Commonwealth of Virginia
2. Overview of regulatory and approving agencies for medical devices and considerations for manufacturers
3. End-to-end process map for Virginia manufacturers
4. Resources to leverage for additional assistance
The Commonwealth is in need of five types of medical use PPE to support healthcare workers, first responders and public works

<table>
<thead>
<tr>
<th>Critical PPE needed</th>
<th>Definition</th>
<th>Quantity Commonwealth is procuring in next tranche (subset of total planned procurement)</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>• N95 respirators: A disposable half-face-piece intended to help reduce wearer to exposure to pathogenic biological airborne</td>
<td>• 5,000,000 units</td>
</tr>
<tr>
<td></td>
<td>• Patient/Isolation masks²: A loose-fitting, disposable device that provides a physical barrier to particulate materials</td>
<td>• 5,000,000 units</td>
</tr>
<tr>
<td></td>
<td>• Exam gloves: A hand covering intended for medical use to prevent contamination</td>
<td>• Vinyl exam gloves: 5,000,000 units, Nitrile gloves: 4,000,000 units, Latex gloves: 4,000,000 units</td>
</tr>
<tr>
<td></td>
<td>• Gowns, non-surgical: A disposable or reusable product intended to protect the user from the transfer of materials in the wearer’s environment</td>
<td>• Isolation gowns: 5,000,000 units, Hair caps: 5,000,000 units, Boot covers: 2,000,000 units, Medical coveralls: 900,000 units</td>
</tr>
<tr>
<td></td>
<td>• Eye protection: A device used to protect the user’s eyes and / or face from bodily fluids, liquid splashes, or infectious materials</td>
<td>• Medical goggles: 1,000,000 units, Face shields: 1,000,000 units</td>
</tr>
</tbody>
</table>

Who the PPE will help:
- Hospitals and Healthcare workers
- First responders
- Public works

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2. Here forward considered Face masks intended for a Medical Purpose that are NOT intended to provide liquid barrier protection
Demand for non-medical use PPE is also increasing as the economy reopens

<table>
<thead>
<tr>
<th>Non-medical use PPE needed</th>
<th>Definition</th>
<th>Indicators of increased demand</th>
<th>Who the non-medical use PPE will help</th>
</tr>
</thead>
<tbody>
<tr>
<td>Filtering facepiece respirators: A filtering facepiece respirator (FFR) offering protection from particulate materials</td>
<td>Global respirator consumption has increased 1,900% since 2019 – from 5B to 100B</td>
<td>General population</td>
<td></td>
</tr>
<tr>
<td>Face masks: A mask that covers the user’s nose and mouth and may or may not meet fluid barrier or filtration efficiency levels</td>
<td>The US PPE market size is expected to grow at a compound annual growth rate (CAGR) of 5.2% - reaching ~$18B by 2026</td>
<td>First responder</td>
<td></td>
</tr>
<tr>
<td>Gloves: A hand covering for the hand for protection against dirt (e.g., nitrile industrial grade gloves)</td>
<td>US states are increasingly requiring residents to cover their faces when in public during the COVID-19 pandemic</td>
<td>Public works</td>
<td></td>
</tr>
</tbody>
</table>

PPE intended for non-medical use is not regulated by the FDA – meaning manufacturers can start producing immediately

Who the non-medical use PPE will help

- General population
- First responder
- Public works

Indicators of increased demand

- Global respirator consumption has increased 1,900% since 2019 – from 5B to 100B
- The US PPE market size is expected to grow at a compound annual growth rate (CAGR) of 5.2% - reaching ~$18B by 2026
- US states are increasingly requiring residents to cover their faces when in public during the COVID-19 pandemic
- Potential that face covers will be required for foreseeable future based on current expert opinions and press search

Notes:
2. Grand View Research; Statista estimates; [ID 895706](https://www.statista.com/); Daedal Research estimates a slightly larger market at ~$15bn
The decision to produce medical or non-medical use PPE has different implications for manufacturers.

<table>
<thead>
<tr>
<th>Types of PPE needed by use</th>
<th>Raw materials needed</th>
</tr>
</thead>
<tbody>
<tr>
<td>N95 respirators</td>
<td>• Spun-bonded polypropylene</td>
</tr>
<tr>
<td>Isolation/patient masks</td>
<td>• Polypropylene</td>
</tr>
<tr>
<td>Exam gloves</td>
<td>• Nitrile, natural rubber, polychloroprene</td>
</tr>
<tr>
<td>Gowns, non-surgical</td>
<td>• Nonwovens (Spunlace, SMS, wet-laid)</td>
</tr>
<tr>
<td>Eye protection</td>
<td>• Polycarbonate, PETG, PVC</td>
</tr>
<tr>
<td>Filtering facepiece respirators</td>
<td>• Various</td>
</tr>
<tr>
<td>Face masks</td>
<td>• Various</td>
</tr>
<tr>
<td>Gloves</td>
<td>• Nitrile, natural rubber, latex</td>
</tr>
</tbody>
</table>

**Message for manufacturers:**

Producing medical use PPE requires additional expertise and access to narrow supply chains.

Producing non-medical use PPE is currently subject to fewer FDA regulatory requirements.

With appropriate labeling, manufacturers can start production immediately for the majority of PPE items needed.

In certain cases (e.g., Class II medical devices), testing may be required, which can take 2 – 4 weeks for approval.
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The FDA, NIOSH and OSHA are the primary agencies involved in the certification, approval, and enforcement of PPE regulations.

<table>
<thead>
<tr>
<th>Agency</th>
<th>Mission</th>
<th>Role relative to PPE</th>
<th>COVID-19 PPE manufacturer resources available (as of April)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Food and Drug Administration (FDA)</td>
<td>Protect public health by ensuring the safety, efficacy, and security of foods and drugs, including medical devices</td>
<td>Sets the regulations and specific performance standards for the majority of PPE</td>
<td>Enforcement Policy for PPE during COVID-19: Immediately in Effect Guidance</td>
</tr>
<tr>
<td>National Institute for Occupational Safety and Health (NIOSH)</td>
<td>Develop new knowledge in the field of occupational safety and health</td>
<td>The CDC agency responsible for the certification and approval of respiratory devices for occupational use</td>
<td>Guidance for Businesses and Employers to Plan and Respond to COVID-19</td>
</tr>
<tr>
<td>Occupation Safety and Health Administration (OSHA)</td>
<td>Assure safe and healthy working conditions by setting and enforcing standards</td>
<td>Sets and enforces standards and provides training to ensure safe and healthful working conditions for employees that may require the use of PPE</td>
<td>Guidance on Preparing Workplaces for COVID-19</td>
</tr>
</tbody>
</table>
The FDA categorizes medical devices across three regulatory classes based on the level of control necessary to assure device effectiveness.

<table>
<thead>
<tr>
<th>Device Class</th>
<th>Regulatory requirements</th>
<th>PPE items in category</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class I</td>
<td>• Exempt from 510(k) marketing approval and design controls</td>
<td>• Non-surgical gowns</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Exam gloves ³</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Scrubs and coveralls</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Head and shoe covers</td>
</tr>
<tr>
<td>Class II</td>
<td>• 510(k) – required if marketing a device for the first time</td>
<td>• Surgical gloves</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Patient/isolation masks</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Surgical gowns</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Surgical N95 respirators</td>
</tr>
<tr>
<td>Class III</td>
<td>• Premarket approval (PMA) – the most stringent regulatory category for medical devices</td>
<td>• None</td>
</tr>
</tbody>
</table>

1. [https://www.fda.gov/medical-devices/consumers-medical-devices/learn-if-medical-device-has-been-cleared-fda-marketing](https://www.fda.gov/medical-devices/consumers-medical-devices/learn-if-medical-device-has-been-cleared-fda-marketing)
2. CDC PPE COVID-19 guidance (23-Mar-2020)
3. Class I (reserved) – subject to premarket notification marketing 510(k) requirements

- The FDA has made exceptions under Emergency Use Authorizations (EUA) to minimize regulatory hurdles to production.
- The FDA regulates devices based on claims made by the manufacturer (e.g., regulated if infection prevention is claimed).
- PPE products marketed to the public for general, non-medical purposes will not require FDA marketing authorization (510(k)); they must be labeled accordingly.
FDA requirements are significantly different during the COVID-19 pandemic compared to “normal” conditions

<table>
<thead>
<tr>
<th>FDA requirements</th>
<th>During normal conditions</th>
<th>High-priority Class I/II PPE as of April 2020²</th>
</tr>
</thead>
<tbody>
<tr>
<td>FDA pre-market notification 510(k)</td>
<td>Depends³</td>
<td>✗</td>
</tr>
<tr>
<td>Registration and listing</td>
<td>✓</td>
<td>✗</td>
</tr>
<tr>
<td>Quality System Regulation</td>
<td>✓</td>
<td>✗</td>
</tr>
<tr>
<td>Reports or corrections/removals</td>
<td>✓</td>
<td>✗</td>
</tr>
<tr>
<td>Unique Device Identification</td>
<td>✓</td>
<td>✗</td>
</tr>
<tr>
<td>Labeling accurately describing intended use</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

**Message for manufacturers:**

The FDA does not intend to object to the distribution of certain items during the public health emergency IF they do not create “such an undue risk”

This risk can be mitigated through:

- Appropriate labeling²
- Demonstrated ability to meet applicable manufacturing and design requirements²

Given frequent policy changes, manufacturers should visit the FDA’s COVID-19 website


1. Electronic Code of Federal Regulations, Title 21, Subchapter H – Medical devices
2. FDA COVID-19 Public Health Emergency Enforcement Policies for (a) Face Masks and Respirators and (b) Gowns, Other Apparel, and Gloves
3. Class I – 510(k) exempt Medical devices do not require a pre-market notification under normal conditions
Product information sheet: disposable surgical N95 respirators

Product description: Surgical N95 respirators, e.g., 3M 8210 and 9210

Product group: Personal Protective Equipment

Usage guidance: Designed for single use. Limited single-wearer re-use considered in contingency scenarios

Current availability: Very low

Technologies required to manufacture: Polypropylene spunbond and meltblown extrusion, heat press & assembly

Degree of automation: Fully automated by large players, but for smaller players the final assembly may be manual (seamstresses)

FDA Classification: Class 2, if surgical — may be 510(k) exempt

Regulatory & compliance validation process difficulty: Medium

Raw material availability: High quality polypropylene likely available; intermediate Spunbond Meltblown Spunbond (SMS) nonwoven, especially the quality meltblown in short supply

Raw material shortages: N95 quality meltblown nonwoven

Design requirements:
- Grade N95
- Good breathability with a design that does not collapse against the mouth (e.g., duckbill, cup-shaped).

Standards: Minimum "N95" respirator according to FDA Class II, under 21 CFR 878.4040; evaluated, tested, and approved by NIOSH as per 42 CFR Part 84

Message for manufacturers:
N95 respirators for medical purposes are likely more difficult to produce for non-medical manufacturers at this time for the following reasons:
- Existing global supply chains are low on raw materials
- After the EUA, regulatory and compliance validation process can be difficult

The FDA authorized all respirators approved by the NIOSH for use by medical personnel during the COVID-19 outbreak
**Product information sheet: Surgical masks**

**Product description:** Surgical masks (these are NOT the same as patient/Isolation masks and face masks)

**Product group:** Personal Protective Equipment

**Usage guidance:** Not intended to be used more than once; discard if damaged, soiled, or if breathing through mask becomes difficult

**Current availability:** Very low

**Technologies required to manufacture:** Polypropylene, typically 2-3 layers; usually in a SMS form

**Degree of automation:** Fully automated by large players, but for smaller players the final assembly may be manual (seamstresses)

**Regulatory & compliance validation process difficult:** Moderate

**FDA Classification:** Class II

**Raw material availability:** polypropylene, polystyrene, polycarbonate, polyethylene

**Raw material shortages:** High quality meltblown nonwoven

**Message for manufacturers:**

Surgical masks must be FDA approved as a Class II Medical device

- Manufacturing standards must meet ASTM F2100 – 19 standard

The Commonwealth expects an extended demand for surgical masks, patient/Isolation masks and non-medical use face masks

**Level 1**

- Fluid protection resistance >80 mmHg
- Differential pressure test <4.0
- BFE (bacteria filtration efficiency standard - 3 μm) ≥95%
- PFE (particle filtration efficiency standard – 0.1 μm) ≥95%

**Level 2**

- Fluid protection resistance >120 mmHg
- Differential pressure test <5.0
- BFE (bacteria filtration efficiency standard - 3 μm) ≥98%
- PFE (particle filtration efficiency standard – 0.1 μm) ≥98%

**Level 3**

- Fluid protection resistance >160 mmHg
- Differential pressure test <5.0
- BFE (bacteria filtration efficiency standard - 3 μm) ≥98%
- PFE (particle filtration efficiency standard – 0.1 μm) ≥98%

**Description**

- Resistance to penetration by synthetic blood
- Breathing pressure difference across the mask
- Ability of the mask to prevent the passage of aerosolized bacteria
- Filtration test using unnaturalized 0.1 micron Polystyrene Latex Spheres

**Standards:** Surgical masks are regulated under 21 CFR 878.4040.

1. ASTM levels determined by ASTM F2100-11 standards, ASTM F1862, ASTM F2299


CURRENT AS OF APRIL 7, 2020

SECRETARY OF PUBLIC SAFETY AND HOMELAND SECURITY

THE WAY AHEAD: PUBLIC SAFETY AND HOMELAND SECURITY

DOCUMENT INTENDED TO PROVIDE INSIGHT BASED ON CURRENTLY AVAILABLE INFORMATION FOR CONSIDERATION AND NOT SPECIFIC ADVICE
Product information sheet: Patient examination gloves

**Product description:** Patient examination gloves (21 CFR 880.6250)

**Product group:** Personal Protective Equipment

**Usage guidance:** Single use, hand hygiene and proper don/doff are critical

**Current availability:** Moderate

**Technologies required to manufacture:** Chemicals (co-polymerization, monomers, plasticizers, Calcium Carbonate/Nitrate baths), rubber molding, ceramic molds, vulcanization, chlorination

**Degree of automation:** Fully automated by large players, but for smaller players stripping ceramic molds typically done manually

**FDA Classification:** Class I – 510(k) exempt

**Regulatory & compliance validation process difficulty:** Low

**Raw material availability:** Uncured nitrile, natural rubber, chemicals, polymers likely available

**Standards:**
- ASTM D6319, D3578, D5250, D6977 or equivalent based on Acceptable Quality Limits (AQL) set by the FDA
- Tensile strength
- Elongation
- Leak test

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1. CDC PPE COVID19 guidance (23-Mar-2020)
2. FDA prohibits powder with Latex gloves because of concerns on impairing wound healing

Source: Derived from manufacturing expert interviews; https://www.fda.gov/media/90612/download; image courtesy of Cardinal Health
CDC guidance states that Level 1 isolation gowns are appropriate PPE for routine COVID-19 patient care\(^1\)

<table>
<thead>
<tr>
<th>ANSI/ AAMI Standard barrier protection</th>
<th>Level 1</th>
<th>Level 2</th>
<th>Level 3</th>
<th>Level 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard use</td>
<td>Minimal Risk</td>
<td>Low risk</td>
<td>Moderate risk</td>
<td>High risk</td>
</tr>
<tr>
<td>COVID-19 applicability</td>
<td>Basic care, standard isolation, standard medical unit</td>
<td>Blood draw, suturing, ICU, or pathology lab</td>
<td>Arterial blood draw, inserting an IV, in the ER, or for trauma cases</td>
<td>Surgery, fluid intense procedures, surgery, infectious diseases suspected</td>
</tr>
<tr>
<td></td>
<td>Routine potential and current COVID patient care</td>
<td>Routine potential and current COVID patient care</td>
<td>Environments that will expose wearer to fluid (e.g., intubations, vomiting patient, etc.)</td>
<td>Surgical purposes and environments that will expose wearer to fluid</td>
</tr>
</tbody>
</table>

Healthcare professionals (HCPs) can use non-surgical isolation gowns when performing routine care for COVID-19 patients\(^2\)

**Non-surgical gowns**
- If gowns are running low, FDA\(^2\) indicates that HCPs can extend the use of disposable gowns without changing between Covid-19 patients. If the gown becomes contaminated, it should be changed.
- **Reusable gowns** (those specifically constructed to be cleaned) should be washed after each patient is treated; can also spray gowns after use with decontamination fluid (ethanol based spray)\(^2\)

**Surgical gowns** should only be used in scenarios where healthcare professionals will be at moderate to high risk of exposure to fluid\(^2\)

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## Product Information Sheet: Non-surgical Isolation Gowns

### Product Information

- **Product description:** Non-surgical isolation gowns (disposable)
- **Product group:** Personal Protective Equipment

### Demand

- **Usage guidance:** Mostly single use, can be re-worn by healthcare professionals if treating known COVID-19 patients
- **Current availability:** Low

### Manufacturing

- **Technologies required to manufacture:** Polypropylene spunbond and meltblown extrusion, heat press, and assembly
- **Degree of automation:** Fully automated for most large manufacturers, smaller manufacturers may use labor (e.g., stitching and cutting)
- **FDA Classification:** Class 1 – 510(k) exempt
- **Regulatory & compliance validation process difficulty:** N/A
- **Raw material availability:** Various (polypropylene, polyester, polyethylene, cotton, blends)
- **Raw material shortages:** Intermediate Spun bond-Melt blown-Spun bond (SMS) nonwoven

### Design requirements

- Isolation gowns (non surgical / non sterile)
- Disposable, common sizes: S, M, L, XL
- Tear resistant, strong seams, low lint, breathability
- Length: ideally to mid-calf
- Back: open or closed (not mandated by CDC)

### Standards

- US: ANSI / AAMI PB70 Level 1 and Level 2 for liquid barrier performance
- European: EN13795, EN14126
- ASTM F4207 for testing of surgical gowns

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1. FDA Medical PPE for infection control
2. CDC PPE COVID-19 guidance (3/23/2020)

Source: CDC; FDA

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Non-surgical isolation gowns are Class I – 510(k) exempt, meaning they can be made and sold almost immediately – including head and shoe covers.
Product information sheet: Eye protection

**Product description:** Eye protection

**Product group:** Personal Protective Equipment

**Usage guidance:** Multi-use, proper don/doff are critical

**Current availability:** Medium

**Technologies required to manufacture:** Injection molding (polycarbonate, polyethylene, PVC)

**Degree of automation:** Partially automated

**Regulatory & compliance validation process difficulty:** Low

**Raw material availability:** Available (polycarbonate, polyethylene, PVC)

**Goggles:**
- Functional: splash protection for eyes; in-directly vented to prevent fogging
- Technical: scratch-resistant lenses
- Shape: snug fit for various face sizes/shapes

**Face shields:**
- Functional: splash protection for face/eyes; clear unobstructed viewing
- Technical: scratch-resistant shield
- Shape: flexible across face of wearer

**Standards:**
- US: Meet specification of ANSI Z87.1-2015\(^1\) (D3 splash marking, not impact resistant rated)

**Message for manufacturers**

Given the FDA does not provide guidance for PPE, manufacturers should refer to ANSI Z87.1-2015 standards and feedback from targeted end-users

Common technologies to produce include injection molding

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1. Eye protection is not classified as a medical device by the FDA, Occupational Safety and Health Administration (OSHA) states that protective eye and face protection devices must comply with specification of ANSI Z87.1-2015, https://www.osha.gov/lawsregs/regulations/standardnumber/1910/1910.133
2. ANSI Z87.1-2015 or additional details at: https://www.coopersafety.com/ansiz87-1

Source: Derived from expert manufacturing interviews; images courtesy of 3M, Pyramex
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3 Understanding end-user PPE needs and assessing internal capabilities will inform the decision to produce PPE

### Understand end-user PPE needs

**Am I interested in helping produce PPE for the COVID-19 crisis?**

- Yes
  - Are end-user PPE needs enough incentive to retool?
    - Yes
      - Proceed to “Identify PPE requirements and technical specifications”
    - No
      - Are end-user PPE needs enough incentive to retool?
        - Yes
          - Proceed to “Identify PPE requirements and technical specifications”
        - No
          - Submit assistance request to VEDP to identify if financial resources are available to support my business

- No
  - Do I have access to the necessary raw materials?
    - Yes
      - Proceed to “Identify PPE requirements and technical specifications”
    - No
      - Do I have access to the necessary raw materials?
        - Yes
          - Proceed to “Identify PPE requirements and technical specifications”
        - No
          - No but I require financial assistance to cover start up expenses
            - Submit assistance request to VEDP to identify if financial resources are available to support my business

### Determine what PPE we are best positioned to produce

- Assess current business model to determine if well-positioned to produce critical PPE

### Identify PPE requirements and technical specifications

- Find alternative ways to support COVID-19 PPE supply efforts (e.g., donate PPE on-hand)

### Produce prototype and test with regulators/end-users

- Leverage GENEDGE resources and manufacturing expertise
- Assistance provided

### Connect with buyers and scale production

- Determine best type of PPE to produce
- Proceed to “Identify PPE requirements and technical specifications”
Proper interpretation of specific manufacturing requirements will help to identify supply chain constraints ahead of time.

Understand end-user PPE needs

- Determine what PPE we are best positioned to produce
- Identify PPE requirements and technical specifications
- Produce prototype and test with regulators / end-users
- Connect with buyers and scale production

For the duration of the COVID-19 pandemic, the FDA has issued EUAs and Enforcement Policies that have temporarily reduced regulatory requirements.

**Decision Points**

- Do I understand the PPE requirements and specifications differences for long-term and short-term (e.g., for COVID duration) manufacturers?
- Do I want to produce PPE for medical use?
- Am I facing additional supply constraints?
- Can I start producing medical-use PPE with my current machinery and equipment?
- Is it a good business decision to produce medical-use PPE?
- For assistance, submit a request to VEDP to identify if financial resources are available to support my business.

**Actions**

- Proceed to “Produce prototype and test with regulators / end-users”
- Seek alternative ways to support the COVID-19 PPE response

**Sub-actions**

- Review the PPE specific FDA, NIOSH, and OSHA requirements within the additional resources
- Consult GENEDGE on technical requirements
- Contact VEDP and/or GENEDGE to leverage additional supply chain resources (e.g., connect with local raw material suppliers)
- Contact VEDP and/or GENEDGE to identify additional equipment requirements and conduct cost analysis
- Consult GENEDGE on technical requirements
- Submit assistance request to VEDP to identify if financial resources are available to support my business.

**Yes – my business is well positioned to source and produce medical-use PPE**
Retooling manufacturers should incorporate targeted end-user feedback and contact Virginia DOLI as early in the process as possible.

### Roadmap:

<table>
<thead>
<tr>
<th>Understand end-user PPE needs</th>
<th>Determine what PPE we are best positioned to produce</th>
<th>Identify PPE requirements and technical specifications</th>
<th>Produce prototype and test with regulators / end-users</th>
<th>Connect with buyers and scale production</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer producing PPE for medical use</td>
<td>Produce PPE prototype</td>
<td>Receive feedback from end users who have reviewed the product</td>
<td>Leverage AAMI, ANSI, ASTM and NIOSH standards for product guidance (see additional resources)</td>
<td>Proceed to “Connect with buyers and scale production”</td>
</tr>
<tr>
<td>Manufacturer producing PPE for non-medical use</td>
<td>Test prototype with targeted end users to inform design</td>
<td>Coordinate with the Virginia Department of Health (VDH) to receive a product review and approval (POC in additional resources appendix)</td>
<td>Did my PPE prototype receive approval from the VDH?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Produce PPE prototype</td>
<td>Coordinate with VDH to ensure PPE products are appropriately labeled for non-medical use</td>
<td></td>
<td>Proceed to “Connect with buyers and scale production”</td>
</tr>
<tr>
<td></td>
<td>Produce PPE prototype</td>
<td></td>
<td></td>
<td>Proceed to “Connect with buyers and scale production”</td>
</tr>
</tbody>
</table>

- If the prototype does not pass VDH approval, seek assistance from VDH and/or GENEDGE to ensure prototype meets the appropriate standards.
- If the prototype passes VDH review, proceed with production.
- If the prototype is for non-medical use, ensure appropriate labeling.
- If the prototype is for medical use, proceed with regulatory approval.

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**Key Points:****

- **Leverage Standards:** Use AAMI, ANSI, ASTM, and NIOSH guidelines.
- **Feedback:** Gather feedback early and frequently.
- **Approval:** Ensure regulatory approval before production scale.
- **Labeling:** Correctly label PPE for intended use.
The Commonwealth and partnering organizations can assist manufacturers with connecting with PPE end-users

**Understand end-user PPE needs**
- Seek guidance from VDH and additional assistance from GENEDGE to work through the approval process

**Determine what PPE we are best positioned to produce**
- Do I meet FDA approval requirements to begin distribution of my PPE?
- Yes → Identify potential buyers
- No → Review FDA requirements and approval process (references provided in Additional resources section)

**Identify PPE requirements and technical specifications**
- Am I connected with a network of buyers?
  - Yes → Schedule delivery of PPE, and be prepared to adjust design based on end-user feedback
  - No → Identify potential buyers

**Produce prototype and test with regulators / end-users**
- Reference eVA to get an updated view of the Commonwealth’s PPE demand signal
- Could I benefit from scaling up production to meet demand?
  - Yes → Continue producing PPE as appropriate
  - No → Do I require additional financial assistance?
    - Yes → Contact VEDP to determine if there are financial resources available to support your production expansion
    - No → I don’t know

**Connect with buyers and scale production**
- Reference eVA to get an updated view of the Commonwealth’s PPE demand signal
- Do I meet FDA approval requirements to begin distribution of my PPE?
  - Yes → Continue producing PPE as appropriate
  - No → I don’t know
- Could I benefit from scaling up production to meet demand?
  - Yes → Reference eVA to get an updated view of the Commonwealth’s PPE demand signal
  - No → Contact VEDP to determine if there are financial resources available to support your production expansion

**Manufacturer producing PPE for medical use**
- Submit request for assistance to VEDP to learn more about Commonwealth business opportunities

**Manufacturer producing PPE for non-medical use**
- Continue producing PPE as appropriate
Commonwealth of Virginia COVID-19 PPE Retooling Playbook contents

1. Descriptions of critical PPE types in demand by the Commonwealth of Virginia
2. Overview of regulatory and approving agencies for medical devices and considerations for manufacturers
3. End-to-end process map for Virginia manufacturers
4. Resources to leverage for additional assistance
### 4 Commonwealth of Virginia resources to support retooling manufacturers with product development and expansion

<table>
<thead>
<tr>
<th>Resource</th>
<th>Role</th>
<th>COVID-19 PPE manufacturer resources available</th>
<th>Point of contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>VEDP</td>
<td>The <strong>Virginia Economic Development Partnership</strong> supports Commonwealth manufacturers with site selection and incentive services for expansion opportunities</td>
<td>Performance-based incentives, including workforce training, to support companies that expand operations with new capital investment and job growth¹</td>
<td><a href="mailto:vbarnett@vedp.org">vbarnett@vedp.org</a> 804.545.5815</td>
</tr>
<tr>
<td>GENEDGE</td>
<td><strong>GENEDGE</strong>, Virginia’s public resource to help manufacturing &amp; industry innovate, compete and grow, is part of the Manufacturing Extension Partnership (MEP) National Network offering tailored and expert business solutions for growth</td>
<td>Comprehensive collection of <strong>COVID-19 Resources for Virginia Manufacturers</strong>, <strong>Video link to Webinar</strong> to assist with understanding medical devices during the COVID-19 pandemic</td>
<td><a href="mailto:dyoung@genedge.org">dyoung@genedge.org</a> 804.801.6000  <a href="mailto:acerilli@genedge.org">acerilli@genedge.org</a> 804.517.1235</td>
</tr>
<tr>
<td>VMA</td>
<td>The <strong>Virginia Manufacturers Association</strong> serves as an advocate for Commonwealth businesses and a resource for training, education, and consulting services to help businesses grow</td>
<td>The <strong>VMA COVID-19 Resource Center</strong>, including daily updates and best practices, a <strong>COVID-19 Model Action Plan</strong> for manufacturers, and the PPE Sourcing Center – a joint effort with McClung Companies</td>
<td>804.643.7489</td>
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</tbody>
</table>

Any entity seeking to sell PPE in Virginia should register at the **Private Sector Portal** to receive updates PPE-related update from Virginia’s Emergency Support Team during the COVID-19 pandemic.

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1. Companies must meet minimum thresholds
# Commonwealth of Virginia resources to assist PPE end-users and manufacturers with testing and evaluation

### Resource
- **The Virginia Department of Health** is leading **Commonwealth efforts** to increase COVID-19 testing, awareness, and evaluating PPE products for medical use during the state of emergency
- **The Virginia Department of Labor and Industry** administers the Occupation Safety and Health program, ensuring employers are complying with relevant laws, standards, and regulations

### COVID-19 PPE manufacturer resources available
- Daily-updated COVID-19 dashboard containing locality information on cases, hospitalizations, and deaths
- Guidance for cloth face covers *(making and wearing)*
- Virginia Occupational Safety and Health’s COVID-19 resources
- Guidance from the Division of Registered Apprenticeship

### Point of contact
- 804.371.2327
- Justin.Paxton@doli.virginia.gov
covid19questions@doli.virginia.gov
- 804.864.7035
- questions@vdh.virginia.gov

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*The Commonwealth’s latest COVID-19 executive actions and press releases identify manufacturing operations as “essential services” – meaning businesses seeking to retool are able to return to work*
Additional resources to support retooling manufacturers

State and local

- The Virginia Small Business Development Center provides COVID-19 resources for small businesses, including the Small Business Debt Relief Program (part of the CARES Act) and industry specific guidance for companies during the Pandemic.
- The Virginia Small Business Financing Authority is the Commonwealth of Virginia’s business and economic development financing arm. It has several programs that may interest retooling manufacturers seeking financial support.

Federal and national

- The Department of Health and Human Services published supplementary information regarding the PREP Act for Medical Countermeasures Against COVID-19, which provides liability immunity to certain individuals for related actions.
- The FDA’s enforcement policies for PPE (face masks and respirators, gowns, gloves and other apparel) during the COVID-19 Public Health Emergency serve as important guidance for industry.
- The CDC’s National Institute of Occupational Safety and Health (NIOSH) provided Interim Guidance for Businesses and Employers to Plan and Respond to COVID-19.
- The Department of Labor’s Occupational Safety and Health Administration (OSHA) released Guidance on Preparing Workplaces for COVID-19 for employers to reference.

The information provided herein does not, and is not intended to, constitute legal advice; instead, all information, content, and materials provided are for general information purposes only and suggested guidance based on the best available information at this time.