



## B.C. Personal Protective Equipment (PPE) Supply, Assessment, Testing and Distribution Protocol

May 1, 2020

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Understanding and implementation of the B.C. Personal Protective Equipment (PPE) Supply, Assessment, Testing and Distribution Protocol (Protocol) requires knowledge of and access to the **PPE Supply, Testing and Distribution Flowchart** (see Appendix A). The flowchart provides a visual representation of the supply, assessment, testing and distribution process.

This document is organized under three themes:

- Supply: How is B.C. sourcing PPE?
- Assessment and Testing: How is B.C. determining the safety and efficacy of PPE prior to decisions about use?
- Distribution: How is B.C. ensuring that appropriate PPE is being delivered to health-care settings in a safe and efficient manner?

### Supply

#### A - Regular PPE from Known Supplier

The Provincial Health Services Authority (PHSA) Supply Chain has long-standing relationships with suppliers that provide PPE from trusted manufacturers. Item models that are already part of the Supply Chain inventory system (e.g. 3M N95 respirators) received from a known supplier can go directly to the PHSA distribution warehouses (see step N) without further assessment or testing.

#### B - Alternative PPE

Due to the COVID-19 pandemic, there is an increasing and unprecedented global demand for PPE and traditional supply chains have been disrupted. The Ministry of Health, PHSA Supply Chain, and regional health authorities are coordinating to pursue all credible leads for PPE with new and existing suppliers. These include known, unknown, or new products from known and unknown suppliers. This means that alternative and/or equivalent PPE is arriving in the province.

Labelling and product documentation will not be trusted blindly in these circumstances. While this PPE may be an entirely suitable and safe option, it must be assessed and tested (see steps G to L) before it is deemed appropriate for use by health-care workers. Each make/model of alternative PPE is assessed to ensure the design is appropriate for use and is also assessed to ensure it meets appropriate integrity and quality parameters.

PPE acquired through the federal bulk procurement process also falls within the category of alternative PPE.

All alternative PPE must be delivered to the PHSA staging area for assessment and testing (see step F).



## C - Fabricated PPE

Several manufacturers and fabricators have offered to produce or begun production of alternative PPE. These products must be delivered to the PHSA staging area (see step F) to undergo the same assessment and testing as with alternative PPE (see step B) to ensure suitability and safety.

## D - Donated PPE

Citizens, businesses, foundations and industries have donated PPE to the health-care system. In the same approach taken with alternative PPE and fabricated PPE, donated products must be delivered to the PHSA staging area (see step F) to be thoroughly assessed before it is deemed safe and appropriate for use in B.C.'s health-care system.

## E - Reprocessed PPE (applies only to N95 respirators)

The Ministry of Health has directed all health authorities, long-term care facilities and assisted living facilities to collect used N95 respirators that are not soiled or damaged for reprocessing; see [PPE Information Bulletin #2](#) for more information.

Used masks will be reprocessed and sterilized using the STERRAD sterilization systems. The U.S. Food and Drug Administration has released an [emergency use authorization](#) to allow STERRAD systems to reprocess N95 during COVID-19. Before COVID-19, the STERRAD sterilization system has been widely used to sterilize medical devices.

Reprocessed respirators are marked as reprocessed. A sample of each reprocessed lot are inspected before they are stockpiled (see step H). **Reprocessed masks will only be used in circumstances where new N95s or tested alternative N95 respirators are not available, and only with explicit direction from the Ministry of Health.**

Standard operating procedures have been developed to guide reprocessing procedures. These procedures have been provided to all regional health authorities, including guidance on how to safely collect and handle used N95 respirators.

## F - Deliver to PHSA Staging Area

PHSA has established a staging area, which is segregated from their main warehouses, to manage the intake, assessment and categorization of PPE.

The purpose of the PHSA staging area is threefold:

- 1) Provide the additional space and loading area required to store large volumes of PPE that is arriving from a variety of sources;
- 2) Segregate untested PPE from the PHSA's warehousing and distribution system to eliminate risk that sub-standard PPE is circulated to health-care workers; and
- 3) Ensure that any PPE that is deemed appropriate for use by health-care workers is moved to PHSA's warehouses and distribution system, with clear information for health-care workers on the efficacy of the PPE and fit-testing requirements.

All PPE that is procured by, or donated to, regional health authorities is to be directed immediately to the PHSA staging area for assessment, testing (see steps G to L) and categorization (see step M).



PHSA Supply Chain is responsible for maintaining a detailed daily inventory of PPE delivered to and leaving from the PHSA staging area.

## Assessment and Testing

The testing process is led by a health and safety assessment and review team that has a combined 100+ years of experience in health and safety – the majority in health care with subject matter expertise in PPE. The team works closely with PHSA Supply Chain, particularly the standardization team, and other stakeholders throughout the entire assessment and testing process. Oversight of the assessment and testing process is the responsibility of the PPE supply working group (see Appendix B).

The determination of whether a piece of PPE is appropriate for deployment will occur through qualitative and quantitative assessment and testing criteria that is collated and determined by an occupational hygienist trained in the approved process.

Steps I to L in the testing protocol (fit testing through to laboratory testing) apply only to respiratory protection. For other PPE such as glove and goggles that require testing, steps F to H would apply – these products would be checked for documentation/certification and manually inspected for any irregularities – prior to categorization (see step M).

### G - Product Documentation: Standard/Certification Validation

Certified PPE typically arrives with appropriate documentation, packing and markings. In the current supply chain environment, documentation from an unknown manufacturer cannot be trusted blindly. Product must be assessed to ensure documentation is valid and the product bears the appropriate labelling.

At the product documentation stage of assessment, alternative PPE (see step B), fabricated PPE (see step C) and donated PPE (see step D) will be assessed to determine if it:

- **Meets and passes all criteria.** In this case, it will move to the next stage of visual and manual inspection (see step H).
- **Is uncertain, unknown or incomplete.** In this case, it will move to the next stage of visual and manual inspection (see step H). If these products pass: visual and manual inspection, fitting characteristic assessment (see step I), as well as quantitative fit-testing (for respiratory protection only, see step J), it will still be required to undergo laboratory testing (see steps K and L).
- **Fails.** These would be cases where the product is determined to be counterfeit or misrepresenting standard/certification approvals. These products will be categorized (see step M) as Category 4 PPE (unacceptable) and will not be used in the health-care environment.

Each type of PPE has specific criteria and requirements for standard/certification or equivalency, as summarized below.

## Respiratory Protection

Respirator protection will be reviewed to determine appropriate certification. If a National Institute for Occupational Safety and Health (NIOSH)-approved respirator, the product will be reviewed to ensure:

- It is on the list of [NIOSH-Approved Particulate Filtering Facepiece Respirators](#);
- NIOSH-approval has not been [rescinded](#); and,
- It is not listed as [counterfeit/misrepresentation of NIOSH-approval](#).



The following are certification standards that are acceptable equivalents to NIOSH:

Country	Acceptable Products	Performance Standard
Australia	P2, P3	AS/NZS 1716:2012
Brazil	PFF2, PFF3	ABNT/NBR 13698:2011
China	KN95, KP95, KN100, KP100	GB 2626-2006
Europe	FFP2, FFP3	EN 149-2001
Japan	DS/DL2, DS/DL3	JMHLW-2000
Korea	1 <sup>st</sup> , Special	KMOEL-2017-64
Mexico	N95, P95, R95, N99, P99, R99, N100, P100, R100	NOM-116-2009

Physical samples will be assessed. If the product is NIOSH-approved, the product will be assessed to ensure it has the [appropriate markings](#).

If respirators are deemed to have equivalency through NIOSH certification or equivalency to international standards, they proceed to the visual and manual inspection step (see step H). If masks are not deemed to have met Canadian or equivalent international standards, they will be categorized (see step M) as Category 4 PPE and will not be used in the health-care environment.

### Masks

Surgical and procedure masks are categorized into one of three barrier levels based on the American Standard Test Method (ASTM) testing and associated fluid resistant to synthetic blood (mm Hg):

- Level 1: 80 mm Hg
- Level 2: 120 mm Hg
- Level 3: 160 mm Hg

Masks will be assessed for the appropriate ASTM standard.

### Gowns

The Association for the Advancement of Medical Instrumentation (AAMI) standards are designed to help medical-device companies meet global standards for the safe use of medical devices. *ANSI/AAMI PB70:2012, Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Health-Care Facilities* classifies gowns according to four levels of barrier performance.

Gowns will be assessed against the AAMI barrier protection certification criteria for appropriateness.

### H - Visual and Manual Inspection

PPE will undergo a visual and manual inspection. This assessment will be conducted to identify quality parameters such as improper seams, improper stitching, material integrity, design irregularities and other non-conformities.



If the items pass visual and manual inspection, they will move on to the next step of fitting characteristic assessment (see step I).

If the item fails visual and manual inspection, it will be categorized as Category 4 PPE and will not be used in the health-care environment.

### **I - Fitting Characteristic Assessment**

PPE products will be assessed to evaluate the overall fitting characteristics for users. This will include a qualitative assessment of the material and associated parameters, such as ties and straps, to determine if it aligns with those regularly used. As appropriate based on the type, PPE will be donned by members of the assessment team and other representatives.

If the item fails this step, it will be classified as Category 4 PPE and will not be used in the health-care environment.

### **J - Quantitative Fit Testing (filtering face piece respirators)**

Quantitative fit testing will be completed using a TSI Portacount Plus fit-test device. Fit testing will be performed in accordance with *CSA Z94.4 Selection Use and Care of Respirators*. Depending on product availability, a minimum of five fit tests will be performed. If there is enough supply, at least 10 fit tests will be performed on different individuals. This step is essential as not all respirators will fit a person's face successfully. In general, a fit test success rate of at least 50% per respirator type is recommended for use as a Category 2 item.

If the item fails the quantitative fit testing step, it will be classified as either Category 3 (not acceptable for use at this time) or Category 4 (unacceptable) and will not be used in the health-care environment.

### **Laboratory Testing (see steps K to L)**

The Ministry of Health is establishing a B.C. PPE testing laboratory capable of industry-standard PPE laboratory testing in collaboration with partners at the University of British Columbia, the National Research Council of Canada, and the Public Health Agency of Canada.

Once operational, this laboratory will offer specialized tests for N95s, surgical/procedural masks, and gowns. In the meantime, laboratory testing of PPE will be contracted to third-party laboratories.

### **K - Laboratory Testing: Particulate Filtration Efficiency**

This section applies only to N95 respirators and surgical/procedure masks.

The particulate filtering efficiency of surgical/procedure masks are tested according to ASTM standards. If appropriate, latex particulate filtering efficiency testing of surgical/procedure masks in the B.C. PPE testing laboratory will be conducted with a latex particulate filtration tester according to ASTM F2299. Latex particulate filtering efficiency testing may also be contracted to third-party laboratories.

The particulate filtering efficiency of N95 respirators are tested according to NIOSH standards. If appropriate, Sodium Chloride (NaCl) particulate filtering efficiency testing of N95 respirators in the B.C. PPE testing laboratory will be conducted with a TSI 8130A tester. NaCl particulate filtering efficiency testing may also be contracted to third party laboratories.



## L - Laboratory Testing: Fluid Resistance

Fluid resistance testing contributes to the classification of surgical/procedure masks into three levels (ASTM 1, 2, 3), with level 1 offering the lowest and level 3 offering the highest level of protection. These tests are performed according to an international test standard, ASTM test method F1862.

Fluid resistance testing in N95 respirators are also tested according to ASTM method F1862.

If appropriate, fluid resistance testing for surgical/procedure masks and N95 respirators in the BC PPE Testing Laboratory will be conducted using a synthetic blood penetration tester as per ASTM method F1862. Fluid resistance testing may also be contracted to third-party laboratories.

Gowns are tested for fluid resistance according to the internationally recognized test standard, *ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health-care facilities*. Fluid resistance in gowns are categorized into four levels (AAMI 1, 2, 3, 4), with level 4 being fluid impervious and the first three levels representing increasing levels of fluid resistance.

If appropriate, fluid resistance testing for gowns in the BC PPE Testing Laboratory will be conducted using a fluid impact tester (AATCC 42) and hydrostatic pressure test (AATCC 127). Fluid resistance testing may also be contracted to third-party laboratories.

## M - Categorization

Based on results of the assessment and testing steps, the PPE will be categorized into one of four categories.

Category 1	Existing inventory item from a known supplier and is in acceptable condition. Has already gone to directly to PHSA warehouse.
Category 2	Not a standard inventory item but: <ul style="list-style-type: none"><li>• meets all required standards; and</li><li>• is acceptable for use; and</li><li>• is in acceptable condition.</li></ul> This PPE tracked within PHSA inventory systems as Category 2 and goes to the PHSA Distribution Warehouse. There must be no distribution of Category 2 PPE until or unless directed by the Ministry of Health.
Category 3	Not a standard inventory item but could be considered for use if B.C. reaches Stage 6 (i.e. no other PPE options) of the PPE Allocation Framework, as it: <ul style="list-style-type: none"><li>• does not meet all required standards; and</li><li>• is in acceptable condition.</li></ul> PPE falling in this category is moved to the PHSA/EMBC Warehouse in Burnaby, ringfenced from any and all distribution channels, until such time, if necessary, that stage 6 of the PPE Allocation Framework is implemented. There must be no distribution of Category 3 PPE unless directed by the Ministry of Health.
Category 4	Item is unacceptable and there is no potential or possibility of it ever being used in the health sector as it:



- does not meet minimal acceptable standards or associated requirements; or
- is not appropriate for use; or
- is in unacceptable condition.

PPE falling in this category is moved to the PHSA/EMBC Warehouse in Burnaby, ringfenced from any and all distribution channels. PPE will be offered to Emergency Management BC for consideration of use outside of the health sector. If the PPE is not deemed useful by EMBC, it must be destroyed.

## Distribution

### N - Deliver to PHSA Distribution Warehouses

PHSA has distribution warehouses in Langley, Victoria, Kelowna, and Prince George. These warehouses serve as the regional supply hubs for regional/local distribution, under direction from PHSA Supply Chain.

Any PPE stored in PHSA distribution warehouses must be either known PPE from known suppliers, or PPE that has been assessed, tested and categorized (see step M) for use under the appropriate stage of the PPE Allocation Framework. To avoid sub-standard PPE making its way into the health system, there shall be no PPE in the PHSA distribution warehouses that is inappropriate for distribution to health facilities. Categorized PPE must be clearly labelled, organized and inventoried (see Step O) to ensure items outside of Category 1 are not distributed without explicit approval from the Ministry of Health.

### O - Organize for Deployment

PPE must be organized for deployment as follows:

- 1) Category 1 and Category 2 items are the only items stored at PHSA distribution warehouses.
- 2) Category 3 and Category 4 items are stored at the PHSA/EMBC warehouse in Burnaby.
- 3) Items stored at the PHSA distribution warehouses must be clearly labelled based on their categorization.
- 4) Category 2 items are not to be delivered to health authorities without direction from the Ministry of Health.
- 5) Prior to delivery of Category 2 items to health authorities, a complete and accurate Product Change Notification (PCN) document must have been distributed in advance. The PCN must include information on the technical assessment/results, a plain-language description on the product and its efficacy, and confirmation that it is a safe and appropriate product based on WorkSafe BC requirements. PCNs require approval by the Ministry of Health prior to distribution.

### P - Deliver to Health Authorities

Delivery to health authorities is managed by PHSA Supply Chain. Health authorities are responsible for identifying need (orders) to PHSA and PHSA Supply Chain, with advice from the PPE supply working group.

Health authorities are encouraged to order PPE based on needs over the next five to seven days. With scarcity of PPE and unreliability of supply chains, providing PPE stock to health authorities for more than one week is not possible.

Health authorities must have central locations to secure their PPE inventory and must allocate PPE to facilities and health-care workers based on the guidance and direction found in the Framework.



In situations of scarcity, allocation of N95 respirators to health authorities will be undertaken under a weighted model that aligns to the proportionality of care resources and consumption drivers that a health authority has. For example, the number of COVID-19 admitted patients, surgical cases, inpatient bed base, and population served are indicators that will be used to determine appropriate allocation of N95 respirators to health authorities.

### **Q - Fit Testing (N95s Only) and Training**

N95 respirators require fit testing to verify a user's ability to obtain an effective seal and an acceptably comfortable fit. Fit testing is done by workplace health/occupational health and safety teams employed by each health authority.

The fit-testing process also provides the opportunity for health-care workers to understand or be reminded of how to properly don, use, and doff the device. The process also provides the opportunity to present and discuss the Product Change Notification with the health-care worker and to address any questions or concerns.

### **R - Health-Care Workers' PPE Use**

The health system must diligently and deliberately conserve, preserve, extend, manage, monitor and use PPE supplies appropriately to ensure the continued availability of these items. The PPE Allocation Framework and subsequent information bulletins provide guidance and direction on appropriate use of PPE.

As per the PPE Allocation Framework, N95 respirators are to be used only for aerosol generating procedures.

### **Relevant Documents**

FDA Emergency Use Authorization for importation of non-NIOSH approved disposable filtering facepiece respirators: [March 28, 2020](#); [April 3, 2020](#).

FDA Emergency Use Authorization for use of expired respirators and/or decontaminated respirators: [March 28, 2020](#).

FDA Emergency Use Authorization for STERRAD systems' decontamination of respirators: [April 11, 2020](#).

Centers for Disease Control and Prevention. [NIOSH-approved N95 Respirators](#).

FDA Appendix A: [Authorized Respirators \(non-NIOSH approved, waived for use\)](#)

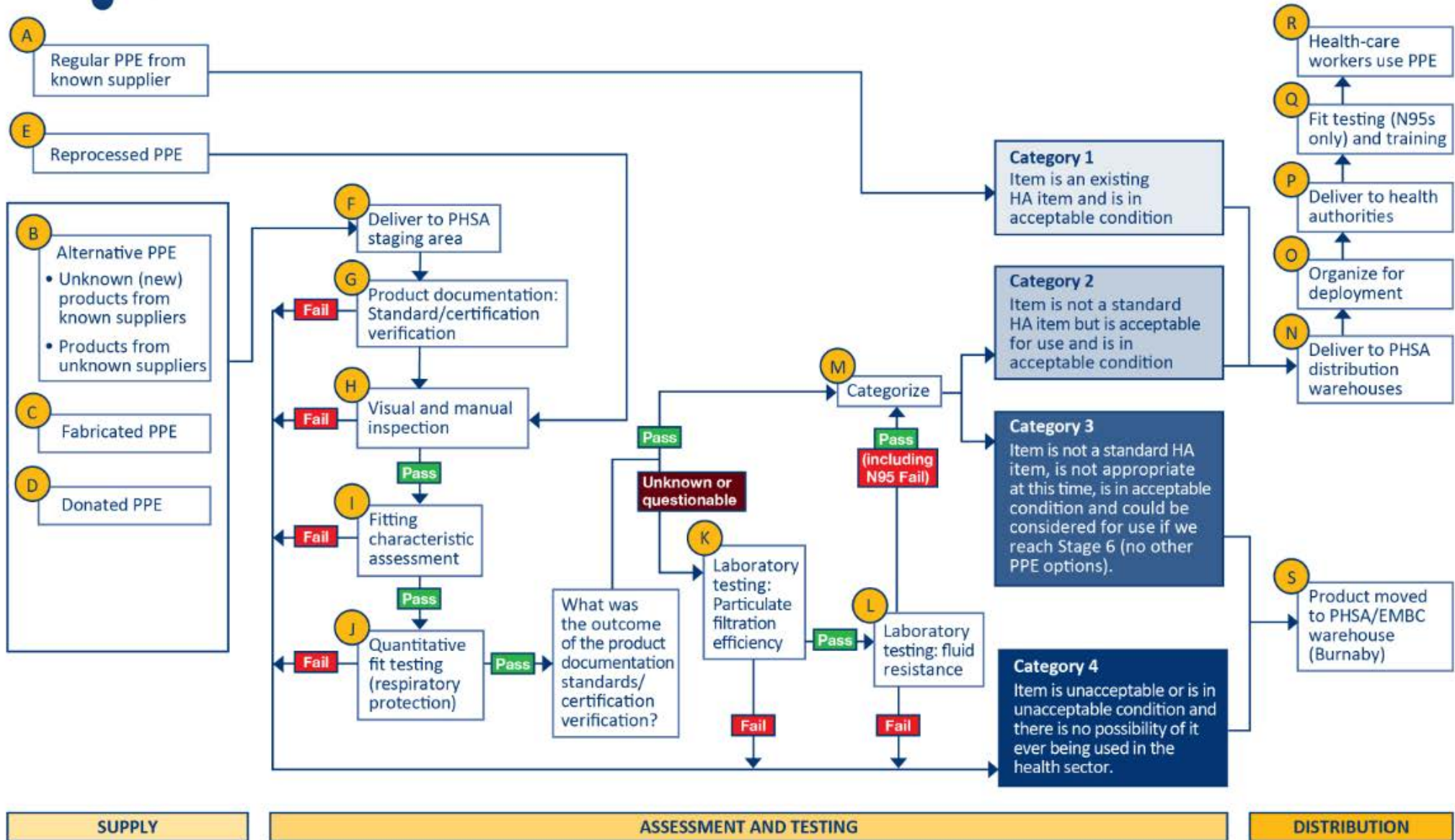


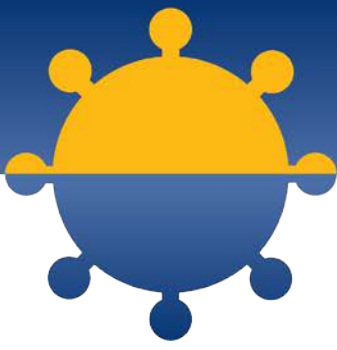


# Coronavirus COVID-19

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## Appendix A: PPE Supply, Testing, and Distribution Flowchart





## Appendix B – Working Group and Review Team Membership

### COVID-19 PPE Supply Working Group Membership

Name	Organization	Role
Stephanie Burniston	HLTH	Project Lead/Research Officer
Quinn Danyluk	FH	Director, Prevention - Health and Safety
Rita Ciconte	FH	Leader, Prevention - Specialized Services
Omid Nobakht	IH	Occupational Hygiene Advisor
Terri Worth	NH	Occupational Health and Safety Advisor
Cameron Wong	PHC	Safety and Hygiene Officer
Nena Benic	PHSA	Occupational Hygienist
Jesse Cooper	VCH	Occupational Hygienist
Wylie Li	VCH	Occupational Hygienist
Andrea Griffiths	VIHA	Prevention Team Leader
Monica Sephton	NH	Infection Prevention & Control
Connie Reid	IH	Coordinator, Medical Device Reprocessing
Coleen Newland	PHC	Clinical Nurse Educator
Lance Storie	PHSA	Inventory Lead, Supply Chain Projects
Maureen Carignan	PHSA	Supply Chain Clinical Coordinator - Standardization
Grant Hunt	PHSA	Provincial Director Warehouse & Logistics
Berna Marcelino	PHSA	Provincial Director Product Standardization
Teresa Johnston	PHSA	In-Hospital Replenishment Lead, Lower Mainland
Sheena Mackay	VIHA	Regional Coordinator - Medical Device Reprocessing
Manraj Chohan	BCEHS	Director, Systems Transformation
Sheree Haydu	BCEHS	Manager, Patient Care Delivery
Mike Michalko	BCEHS	Director, Business Standards and Evaluation
Albert Csapo	VCH	Utilization Director, Perioperative Services
Brittany Watson	VCH	Prof Practice Director, Nursing and Allied Health

### PPE Review Team

Team Member	Subject Matter Expertise	Degree/Certification
Joel Odin	Health and Safety Professional Team Leader	Health and Safety Diploma Canadian Registered Safety Professional



Dave Buhr	Health and Safety Professional	Health and Safety Diploma Canadian Registered Safety Professional
Lorne Baron	Health and Safety Professional	Health and Safety Diploma Canadian Registered Safety Professional
Tina Chiang	Occupational Hygienist	MSc (Occupational Hygiene)
Hanchen (Phil) Chen	Occupational Hygienist	MSc (Occupational Hygiene) Certified Industrial Hygienist Registered Occupational Hygienist

### PPE Laboratory Testing Team

Team Member	Subject Matter Expertise	Team Role
Titus Wong, MD, MHSc, FRCPC	Medical Microbiology, Infection Prevention and Control	Team Leader/ Medical Lead
Allison Muniak, MASc	Human Factors Engineering, Quality Management	Operations Leader
Rachael Ritchie, DPhil	Laboratory Management, Research & Test Development	Project Coordinator
Julie Frketich, MLT	Quality Management, Accreditation	Quality Management Lead
Jesse Cooper, MSc	Occupational Hygienist	Manager, Technical Leader
Matty Jeronimo, BSc	Occupational and Environmental Hygiene	Technical Specialist
Brendan Gribbons, P.Eng, M. Eng	Biomedical Engineering	Biomedical Engineering Expert
Andrew Hurlburt, MD, FRCPC	Infectious Diseases, Infection Prevention and Control	Scientist
Katherine Plewes, MD, PhD, FRCPC	Infectious Diseases, Infection Prevention and Control	Scientist



Raymond Lim, B.Eng	LEAN, Process Improvement	LEAN & Process Advisor
Matthew Harraway, RSE	Facilities, Maintenance and Operations	Construction, Facilities Maintenance

*Additional members: Albert Csapo, Elizabeth Bryce, Mandy Man, Nicky Huang, Florinda Angeles, Jennifer Irwin, May Chan*

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Ministry of Health



BC Centre for Disease Control

**If you have fever, a new cough, or are having difficulty breathing, call 8-1-1.**

