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Health Canada
Health Products and Food Branch
Medical Devices Directorate

Optimizing the use of personal respiratory protective devices during the COVID-19 outbreak

The use of personal respiratory protective devices, respirators and masks, during the COVID-19 outbreak is essential to slowing the spread of the disease across Canada and to protecting healthcare professionals. Health Canada, as the regulator of medical devices in Canada, provides this guidance to optimize supplies of respiratory devices for use in healthcare settings when supply is limited. It is important to note that the optimal way to prevent transmission of infectious agents is to use a combination of interventions from across the hierarchy of controls, not just personal protective equipment alone.

The positions presented in this document are intended to address potential shortages of respiratory devices. The document is for internal use by Health Canada and the Public Health Agency of Canada. It will serve as a foundation to develop content to publish on Health Canada's website to inform healthcare professionals, provincial and territorial institutions, other government organizations, as well of the general public. The need for this guidance will be reviewed in one year from the publication of information on Health Canada's website or by March 31, 2021.

A definition for respirators and masks is provided on the Public Health Agency of Canada' s (PHAC) website.

N95 respirators for medical applications

N95 particulate filtering face-piece respirators (N95 respirators) indicated for use in medical applications are considered Class I medical devices in Canada. They are manufactured in licensed establishments. Companies that hold a Medical Device Establishment Licence for manufacturing N95 respirators indicated for use in medical applications in Canada may be found on the Medical Devices Establishment Listing.

N95 respirators are respiratory protective devices designed to achieve a minimum filtration efficiency of 95% when worn properly. The edges of the respirators are designed to form a seal around the nose and mouth. N95 respirators are produced in many different styles, such as cupstyle (seen below), flatfold or duckbill, and may or may not be equipped with an exhalation valve.

In a healthcare setting, respirators (N95 filtration level or higher) protect against inhalation of biological aerosols including viruses and bacteria. PHAC recommends the use of NIOSH certified respirators equivalent to N95 or greater to prevent the inhalation of varicella zoster virus (chickenpox),

Mycobacterium tuberculosis, rubeola virus (measles), smallpox, monkeypox; and when aerosol-generating medical procedures (e.g., intubation, bronchoscopy) are performed on patients suspected or confirmed to have a viral hemorrhagic fever (Ebola, Lassa, Marburg, Crimean-Congo viruses), SARS, MERS-CoV, COVID-19, and emerging and/or novel viruses.

The respirators are evaluated, tested and certified by NIOSH and must pass minimum performance requirements, such as filter efficiency and breathing resistance. All N95 respirators certified by NIOSH must have an approval number stamped on the respirator represented as TC-84A-####n the Indication of NIOSH and N95. Health Canada accepts the NIOSH certification of N95 respirators as an appropriate quality standard for respirators used by healthcare professionals. Equivalent alternate standards are also acceptable, like European standard CE FFP2.

The Use of N95 respirators beyond their shelf life

Most respirators have a limited shelf life, after which they are intended to be discarded. The length of time a respirator is stored beyond its shelf life or recommended conditions of storage may affect its performance. This includes not only the filter media but also headbands and nose foam components, which may affect the seal that is created. N95 respirators that are past their manufacturer-designated shelf life are no longer considered NIOSH-approved, as all manufacturer-designated conditions of use must be met to maintain the NIOSH approval. However, in times of increased demand and decreased supply, consideration can be made to use these expired N95 respirators.

As expired respirators can still serve an important purpose, healthcare facilities should retain all expired N95 respirators for use during the pandemic. This recommendation is made because healthcare services are essential and must continue in the face of the COVID-19 outbreak. There is no specific timeframe beyond the expiry dates for N95 respirators at which they would no longer be considered suitable for use. Expired respirators can still be effective at protecting workers if the straps are intact, there are no visible signs of damage, and they can be fit tested. Before use, healthcare professionals should inspect the respirators and perform a seal check.

NIOSH has issued a limited list of expired N95 respirators that have been retested and still meet certification.

Masks (surgical, procedure, medical)

Masks, for example surgical masks, are devices that are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and operating room personnel from the transfer of microorganisms, body fluids and particulate material. There are 3 classifications under the American Society for Testing and Materials (ASTM) 2100:

- Level 1 low (venous pressure splash)
- Level 2 moderate (arterial pressure splash)
- Level 3 high (high-velocity procedures, orthopedic surgery, etc.)

Typical surgical masks do not provide the same level of filtration as a NIOSH approved N95 respirators as they are neither tight-fitting nor capable of providing sufficient filtration over a wide range of particle sizes. PHAC recommends the use of masks for healthcare professionals as part of comprehensive system to prevent transmission of infection in healthcare settings, known as Routine Practices and Additional Precautions.

The use of masks beyond their shelf life

The use of masks beyond their shelf life can still serve an important purpose. Therefore, healthcare facilities should retain all expired masks for their use during the pandemic. There is no specific timeframe beyond the expiry dates for masks at which they would no longer be considered suitable for use. Masks can still be effective at protecting workers if the straps are intact and there are no visible signs of damage. Healthcare professionals need to check the integrity of the mask before its use.

Non-medical N95 Respirators

Occupational (commercial-grade) N95 respirators and medical-grade N95 respirators are of similar structure and design; however the manufacturing setting and the quality management system applied may differ. N95 respirators for medical indications are manufactured in a clean-room environment while non-medical respirators are not necessarily. The main difference between the two grades is that commercial N95 respirators are not tested for fluid resistance of any type, including the ASTM Test Method F1862 "Resistance of Medical Face Masks to Penetration by Synthetic Blood", which determines the respirator's resistance to synthetic blood directed at it under varying high pressures. This test is not considered essential in the current pandemic circumstances, as the wearer is seeking protection from biological aerosols (droplets).

The use of commercial-grade N95 respirators

Healthcare professionals may consider using commercial-grade N95 respirators as personal protective equipment in healthcare settings during response to the COVID-19 outbreak if alternatives are not available.

Importing or distributing non-compliant PPE

Manufacturers and importers seeking to import non-compliant products (e.g., non-bilingual labels, products beyond their shelf life, non-medical grade products) should take the following steps:

- Complete the attached notification form ***HC Personal Protective Equipment (PPE) - Notification form***

- Send the completed form along with a copy of their product label to: hc.mdel.questions.leim.sc@canada.ca
- Include “COVID - Notification” in the subject line of the email to help Health Canada prioritize and expedite requests.

Expediting Authorization of Personal Protective Equipment in Canada
Health Canada will expedite the review and issuance of Medical Device Establishment Licences (MDEL) for companies requesting to manufacture, import or distribute Class I PPEs. Health Canada’s goal is to review and issue MDELs within 24 hours from the time a completed application is received.

Companies that need an MDEL application expedited should do the following:

- Complete the MDEL Application Form (FRM-0292) available on Health Canada’s website.
- Indicate the following in the subject line of their email: URGENT COVID-19 MDEL application for “name of company.”
- Email the completed MDEL application form to hc.mdel.application.leim.sc@canada.ca.

Applicants are requested to indicate the following in the subject line of their email: URGENT COVID-19 MDEL application for “name of company”.

Authorization of respiratory devices by the US FDA
On March 2, 2020, the US Department of Health and Human Services (HHS) informed PPE manufacturers and strategic stockpilers that they were able to submit a request to the US Food and Drug Administration (US FDA) to have their products added to the Emergency Use Authorization (EUA). A list of authorized respirators was published on March 16, 2020.

Details can be found on the US FDA website, which lists EUAs for diagnostic tests and personal protective equipment.

There is a section for "NIOSH-Approved Disposable Filtering Facepiece Respirators for Use in Health Care Settings During Response to the COVID-19 Public Health Emergency." All relevant documents and strategies related to the designation are posted there.

Approved by

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