COVID-19 Media Lines

N95 Masks – Decontaminating and Reuse

Issue Statement: The current COVID-19 pandemic is dramatically increasing the demand for personal protective equipment (PPE) and putting strain on the global supply of single use N95 respirators. Because of potential shortages of PPE during the COVID-19 response, the Government of Canada is working with manufacturers to identify technologies that enable effective decontamination of single use N95 respirators, which would allow their safe reuse by frontline healthcare professionals. The Government of Canada is considering the decontamination and reuse of N95 respirators along with other strategies, such as the use of expired masks, in addition to procurement and increased domestic production, to ensure the continued availability of these devices for frontline healthcare response. This approach has been successful in other countries, including the United States.

Key Messages:

- The N95 masks used by healthcare workers are labelled as single-use products.
- The Government of Canada, like many other countries, is looking at ways to extend the use of personal protective equipment (PPE), such as N95 masks, through decontamination as a way of helping Canada meet its supply needs.
- The Government of Canada has asked provinces and territories, as well as healthcare providers, to keep their used N95 masks and store the masks according to their local biosafety standards and guidelines while we verify processes for successful mask decontamination.
- Health Canada has already authorized certain machines to decontaminate N95 masks under the Interim Order for Medical Devices. Products and manufacturing processes must meet the requirements for safety, quality and effectiveness to protect the health and safety of Canadians.
- The Government of Canada has procured decontamination units to increase provincial and territorial capacity to reprocess N95 masks, if needed.
- Other countries, including the United States, have taken this approach.
- The Government of Canada is working hard to get PPE and medical supplies to healthcare workers through bulk procurement in collaboration with the provinces and territories, ramping up domestic production capacity, and identifying potential alternatives and ways to extend product life.

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On the Public Health Agency of Canada's Procurement of Decontamination of Devices for the Reprocessing of Single Use N95 Respirators during the COVID-19 Response

- The Government of Canada put in place a contract with Stryker Canada, on April 15, 2020, to procure 82 decontamination devices.
- These units will provide a total additional national capacity to reprocess approximately 275,500 N95 respirators a week.
- These devices are the result of Canadian research and development efforts and are manufactured in Canada.
- The Government of Canada continues to work closely with all provinces and territories on their potential needs for additional decontamination and reprocessing capacity.
- The National Research Council has purchased 20 Clean Flow Healthcare Mini medical devices to share with hospitals to study mask decontamination.

On Health Canada's Considerations for the Reprocessing of Single Use N95 Respirators during the COVID-19 Response

- The Government of Canada recognizes that reprocessing masks is a potential solution that would provide an additional supply of masks for healthcare workers who rely on them for protection.
- Because of potential shortages of PPE during the COVID-19 response, the Government of Canada continues to work with manufacturers to identify additional technologies that enable effective decontamination of single use N95 respirators, which would allow their safe reuse by frontline healthcare professionals.
- Decontamination is an acceptable way to make the masks safe for reuse. Companies are required to provide evidence that demonstrates their processes are capable of adequate decontamination for reuse.
- Health Canada has posted a notice to inform manufacturers of important regulatory requirements that would need to be considered to demonstrate that their decontamination methods for single use N95 respirators would meet key safety and effectiveness requirements.
- A notice with important considerations for healthcare professionals has also been posted that provides further information about Health Canada's evidence requirements ensuring that products and manufacturing processes meet the standards required for safety, quality and effectiveness.
- Manufacturers wishing to reprocess medical devices for use for COVID-19 can apply for expedited authorizations under the March 18, 2020 Interim Order—a streamlined regulatory process to respond to the health crisis.

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- There are two approaches that may be taken:
  - companies may provide sterilization or decontamination devices or systems to healthcare facilities for use in reprocessing single use N95 respirators, or
  - companies may themselves reprocess and redistribute single-use N95 respirators to healthcare facilities.

- Healthcare facilities with sterilizers capable of reprocessing N95 respirators in house do not require Health Canada authorization to conduct the activity. However, Health Canada highly recommends that healthcare facilities use only technologies that have been authorized by Health Canada.

- The Government of Canada continues to engage with the healthcare community, and provinces and territories to monitor the supply of PPE, as well as options for reprocessing N95 masks.

- Our goal is to identify options quickly and to effectively address the healthcare community's critical need for safe and effective PPE.

Authorizations under the Interim Order for Medical Devices

- Health Canada has invited applications from medical device companies with extensive experience manufacturing the equipment used in decontamination and reprocessing to authorize these technologies to safely and effectively reprocess N95 respirators and other PPE. As with all COVID-19-related products, Health Canada is expediting applications for these products and making them our top priority.

- Under the Interim Order for Medical Devices (link), Health Canada has authorized expanding the intended use of sterilizers and authorized new devices to reprocess N95 respirators.

- A list of the authorized devices is available here (look for "sterilizer" or "decontamination" under the "technology" column). This list will be updated regularly as devices receive authorization.

- Health Canada will continue to monitor current international trends and assess the evidence supporting various decontamination and sterilization methods/strategies for the reprocessing of other PPE such as single use surgical masks in the context of the COVID-19 pandemic.

On existing guidance

- In May 2016, Health Canada published a notice to industry on re-use of single-use medical devices.

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- Companies that reprocess and distribute medical devices originally authorized and labelled for single use to Canadian healthcare facilities will be held to the same Health Canada requirements as manufacturers of new devices.

- Each manufacturer of an authorized sterilizer or decontamination device has their own guidelines to provide details to users on how to operate it for the purpose of decontaminating respirators, including:
  - Instructions for healthcare facilities;
  - Instructions for healthcare personnel; and
  - N95 decontamination fact sheet.

- A notice with important considerations for healthcare professionals has also been posted that provides further information about Health Canada's evidence requirements ensuring that products and manufacturing processes meet the standards required for safety, quality and effectiveness.

On the Report to the Chief Science Advisor of Canada: Task Force on N95 Face Masks Reprocessing

- Experts from PHAC and Health Canada were among the members of the Task Force that examined available evidence on reprocessing and re-use of N95 face masks (also referred to as N95 respirators or respirators) in light of potential shortages of these devices.

- The Task Force conducted an expedited review of options for mask reprocessing using ultraviolet light, heat/microwave and chemicals such as hydrogen peroxide.

- The recommendations made in this report are in line with the current practices and plans supported by PHAC and Health Canada.

- Since the report was submitted, Health Canada has approved additional technologies for reprocessing. The Department continues to assess all technologies related to COVID-19 in an expedited manner.

Questions and Answers:

Q1. What are the potential decontamination methods under evaluation?
Several proposed systems of decontamination are being assessed in Canada and around the world. The decontamination systems already authorized (e.g., Stryker Sterizone VP4 Sterilizer, Sterrad sterilization systems, Steris sterilization systems, Clean Works Clean Flow Healthcare Mini, and Bioquell Hydrogen Peroxide Vapour Generator) use various methods including, vaporized hydrogen peroxide, ozone or ultraviolet light. There is ongoing evaluation of new decontamination methods as applications are submitted under the Interim Order for medical devices.

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Health Canada assesses proposed methods to ensure they meet the standards required for safety, quality and effectiveness and that the requirements for the key performance and safety endpoints to ensure the integrity of N95 are maintained following reprocessing to the validated limit of reprocessing cycles.

Q2. Is there good evidence to support these methods?
Although the virus that causes COVID-19 is a novel virus, evidence from previous studies using similar viruses supports the safety and effectiveness of some reprocessing methods.

Manufacturers will be required to provide evidence to demonstrate the safety and effectiveness of their selected method of decontamination.

At a minimum this includes:

- disinfection of all harmful organisms (e.g., bacteria and viruses) likely to be present in the standard medical setting;
- demonstration that respirator filter and fit performance are maintained;
- evidence that there are no residual chemical hazards related to reprocessing; and
- ensuring adequate labelling that describes validated methods and reprocessing conditions applied to the respirator.

Q3. What are the drawbacks to reprocessing versus new masks?
Health Canada recognizes that reprocessing single-use masks is one potential solution to provide continued access to masks for healthcare workers who rely on them for protection.

Instructions from each manufacturer of an authorized decontamination device should be followed.

Fit is an extremely important aspect of N95 use. The drawback for reprocessed N95 mask versus new mask is that the nosepiece has been bent and may not allow a good fit. This is why PHAC recommends that respirator be returned to the original wearer, to increase the likelihood of fit. Should the reprocessed mask be put back into general circulation, it becomes very important to undertake the standard user seal check and to only use those masks that fit the user's face.

Q4. Have other regulators approved decontamination methods? Are we also considering these?
Health Canada is aware that a number of devices have received Emergency Use Authorization (EUAs) from the US Food and Drug Administration to reprocess N95 masks (link). Health Canada continues to evaluate guidance from other agencies such as the US Centers for Disease Control and Prevention (CDC) for optimizing the re-use of respirators.

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