Frequently Asked Questions about N95 Collection and Reprocessing for Medical Device Reprocessing (MDR) Staff
Updated May 22, 2020

- **Why are we collecting N95s for possible future reprocessing?**
  NSHA has developed a strategy to balance supply and demand of our PPE. We have discussed the needs to manage our supply between shipments and **NSHA has N95 supply to meet current needs.**

  As we move forward with our planning, we are preparing for all scenarios, including the potential of reprocessing. This is a back-up measure to prepare for any possible N95 shortage in the future.

  We are collecting N95s for **possible** reprocessing and will be launching further N95 conservation measures. **We have begun rolling out our collection strategy in targeted, high-use areas, such as ICUs, emergency departments, perioperative and COVID units.**

  We are doing this to make sure that those staff and physicians who need an N95 to provide care safely could continue to access them even if we reached a point in the future where there was a shortage of supply. **We are NOT asking staff to wear reprocessed N95 respirators at this time.**

- **What is MDR's role in N95 reprocessing?**
  NSHA executive leadership has indicated that all reprocessing efforts related to COVID-19 will flow through the PPE Working Group for planning and logistical purposes.

  However, MDR will be reprocessing the N95s, as they have the expertise and the capacity to meet this need.

- **There is no way to pre-clean the N95 respirators before putting them into our VPro machine (low temperature sterilizing method that uses hydrogen peroxide) so how do we protect MDR staff who are handling them?**
  MDR technicians will wear the recommended PPE for handling soiled items including gloves, gown, surgical mask/face shield.

- **How can we be sure that reprocessing of N95s is safe and effective?**
  Teams from Research, Medical Device Reprocessing, Infection Prevention and Control, Infectious Diseases, Occupational Health & Safety, and Industrial Engineering have been working to identify safe, evidence-based reprocessing methods that could be put in place quickly to allow safe re-use of N95 respirators. NSHA is following Health Canada, CDC and FDA guidelines for approved and validated reprocessing methods. Of note, the reprocessing

process ensures:

1. The pathogen burden has been removed or reduced to limits acceptable by Health Canada.

2. Filtration efficacy is maintained as per original specifications. Maximum number of lifecycles is considered. Efficacy depends on the technology used. For e.g. V-PROs will be able to reprocess certain N95 masks up to 10 times.

3. There are no residual chemical hazards as a result of reprocessing.

Users must test personal fit/seal and mask composition at each use.

- **These contaminated masks will be transported to our facility in card board boxes. How can we ensure the staff transporting these are not contaminating themselves, the truckers, our shipping and receiving staff and MDR staff who have to handle these masks before placing them in the VPro machine?**
  The used respirators will be placed in ventilated boxboard boxes for storage and subsequent transportation to the reprocessing site. Transport totes and/ or case carts will be used to store and transport. A standard operating procedure will be developed to ensure safety in handling, similar to procedures already used for handling contaminated medical devices.

- **What PPE do MDR technicians wear to handle and reprocess N95s?**
  MDRTs will wear the recommended PPE for handling soiled items including gloves, gown, surgical mask/ face shield.

- **What processes have been put in place to ensure the N95s are protected from contamination after reprocessing is complete?**
  This process will be developed by subject matter experts in both MDR and Infection Prevention & Control to ensure safety and integrity of the reprocessed respirator.

- **If we have to reprocess N95s, will they go back to the original users?**
  We will not be labeling N95s for return to original users at this time. However, the working group tasked with planning and implementation of this work will adhere to regulatory requirements to ensure the highest degree of staff and patient safety. Reprocessing will ensure removal of viral and bacterial load; reprocessed N95s will be safe to use and only distributed as a last resort.

- **How can we ensure reprocessed N95s are safe and effective in protecting staff after multiple users have worn them?**
  Quality checks will be in place to ensure N95s are reprocessed effectively and are safe for use. Every person who dons an N95 will be required to do a seal

check with the same style respirator they were fit tested to; if the seal is unable to be achieved, the respirator cannot be worn. MDR staff are the subject matter expertise and the working group will draw on MDR's expertise to work through a viable solution.

- **What PPE will be given to those operating the machine?**
  PPE will be based on the tasks the staff member is performing. At a minimum, they would be wearing gloves, gowns and a surgical mask. Infection Prevention and Control and Occupational Health, Safety and Wellness are engaged in ensuring staff are trained, provided with PPE recommendations, and supplied the appropriate PPE.

- **What will be the total N95 mask sanitization processing time?**
  A small cohort of MDR staff will be assigned to implement N95 reprocessing. Each reprocessing modality requires different processing times and can reprocess different volumes.

- **What is the difference between sanitization and sterilization?**
  Sterilization is the complete removal of all living or viable organisms on an object. Items that come in contact with sterile body cavities or the vascular system (e.g. during surgery) must be sterilized.

  Sanitization reduces the population of microorganisms on environmental inanimate surfaces and objects but does not destroy or eliminate all microorganisms, e.g. we regularly use alcohol-based hand sanitizer to perform hand hygiene. While we will not make the statement that our technologies produce a sterilized N95, we do know that in order to receive Health Canada approval, manufacturers must demonstrate that they have achieved bacterial sporicidal kill (e.g. *Bacillus stearothermophilus* spores) and viral inactivation (e.g. SARS-CoV-2, H1N1). Spore-forming pathogens are the most difficult to kill and the technologies we are implementing have been able to demonstrate this high level of pathogen reduction.

- **Why are different processes being implemented across the province?**
  All processes being used by NSHA are approved by Health Canada. Smaller sites will have a lower level of use and need, so could use a technology that reprocesses smaller volumes.

  In the early days of the pandemic, procuring equipment was challenging due to a competitive global environment. As a result, we decided to purchase several different modalities that could support provincial reprocessing capacity. As much as possible, we wanted to use technologies already in place and used in regular operations so that staff would already be trained and familiar with how to use.

The two main technologies that will be implemented first have been used for N95 reprocessing in other organizations across Canada:

- a low temperature sterilizer that sanitizes respirators using hydrogen peroxide
- a larger volume unit that sanitizes respirators using a combination of hydrogen peroxide vapour, ozone and ultraviolet light.

Standard Operating Procedures have been developed for these processes and include rigorous quality assurance checks.

- **Why are we not just relying on technologies we already have and are familiar with using, such as the VPros (low temp sterilizers)?**
  In the early stages of this pandemic, mathematical modeling was conducted to try and determine burn rates (utilization rates) for N95s. Based on the provincial burn rate calculated and the throughput modeling for the VPRo technology, it would have been significantly ineffective in maintaining a provincial supply. As a result, a decision was made to procure technology, approved by Health Canada that could sanitize large volumes quickly (800-1000 N95s per day). Additionally, VPros are crucial in supporting clinical needs both during pandemic slowdowns and as services begin to ramp up.

- **What validation process will you use to ensure a mask has been properly sanitized?**
  Manufacturers would have performed validation testing in order to receive Health Canada approvals. We are working with Medical Device Reprocessing (MDR) and the lab to standardize the Quality Assurance (QA) processes. Reprocessing and release (if ever required) will only start once QA processes have been completed. Each modality that is being used has been validated against the requirements set out by Health Canada either by the manufacturer or by NSHA itself under provincial jurisdiction & oversight. That ability is embedded under the Interim Order in Canada process. Regularly occurring quality indicator checks will be used during reprocessing cycles.

- **The Q&A notes that masks will not be returned to the original user; however, from the information I could find machine manufacturers are recommending the mask be returned to the original user. Why the deviation from recommendations?**
  This practice is variable in other jurisdictions with some choosing to identify PPE for re-use by the original user, and others approaching it as a universal supply and broadly distributing reprocessed N95s. We've heard from many end users who wanted to know that we have enough confidence in reprocessing that it is as safe to go back to another person as it is to return to the original user.

  As an organization, we will only use a modality that meets the specific safety

requirements outlined in the *Notice – Important Regulatory Considerations for the Reprocessing of Single Use N95 Respirators during the COVID-19 Response*.

- **What type of containers will be used for respirators that have been reprocessed?**
  The type of container used for reprocessed respirators will depend on the modality used to reprocess. If a VPro is used, reprocessed N95s would be placed in a sealed pouch. If Clean Works or UV are used, reprocessed N95s will be placed in non-vented boxes.

- **I understand reprocessed masks will only be used in a worst case scenario. Are you considering reprocessing a mask more than once?**
  Yes, different modalities have been validated for a specific number of reprocessing cycles and we will ensure this monitoring requirement is captured in the SOP.

- **If yes, how will you identify/track how many times a mask has been reprocessed?**
  Each time an N95 respirator undergoes a reprocessing cycle, MDR staff will mark it with a tick. Once it has undergone its maximum number of cycles, it will be discarded. It will also be discarded if there is any evidence that the integrity has been compromised. This will be incorporated into the SOP.

- **Will the user know the mask they are using has been reprocessed and how often it has been reprocessed?**
  Yes, staff will know based on the label on the box/ pouch in which the reprocessed N95 will be packaged, as well as tick marks indicating the number of times it has been reprocessed.

- **Will you issue a communication to all staff if/when you start issuing reprocessed N95s?**
  Yes, we will communicate to staff and physicians if/when we start issuing reprocessed N95s. They will also know based on the label on the box/ pouch if they missed a message.