

Information Note
Department of Health and Community Services

Title: N95 Masks – Removal of Counterfeit Masks from Inventory

Issue: Shared Services-Supply Chain determined that a quantity of 3M N95 masks in current inventory are counterfeit.

Background and Current Status:

- During the pandemic, the demand for N95 masks increased exponentially worldwide.
- As established vendors were unable to meet the demand, procurement activities had to expand to vendors who were not necessarily authorized by N95 manufacturers (e.g., 3M). Shared Services-Supply Chain (SS-SC) contracted with a number of vendors to build an inventory of N95 masks.
- Supply Chain purchased N95 1860 model masks in October 2020 from Bergwater, a local NL supplier, in response to COVID-19. The procurement process included getting samples from the supplier that were reviewed and approved by OH&S. Documentation was received by the supplier to validate the quality of these masks. An SGS (a global brokerage/inspection firm) inspection was also conducted.
- On December 18, 2020, 3M posted a notification, including lot numbers, on their website of fraudulent/counterfeit N95s. 3M did not send this notification to customers.
- On January 6, 2021, SS-SC became aware of the 3M notification and checked their 3M N95 inventory. It was determined that 100,560 counterfeit masks were entered into inventory in late November 2020, with 1320 of these being issued to facilities in Eastern Health, Central Health and Western Health. These masks were purchased from the vendor, Bergwater, an NL company, which is not an authorized 3M distributor.
- SS-SC staff immediately began to recall the 1320 masks from the RHAs and were successful in retrieving 1140 items, leaving 180 N95s unaccounted for by early morning, January 7, 2021.
- The items retrieved have been examined by RHA Occupational Health and Safety (OHS) staff. An initial review determined that the items are 1cm larger than other 3M masks, and that they appear to be made of lower quality materials; however, testing had not yet occurred to determine if filtration standards are met.
- A communication is being circulated within health care facilities requesting staff to look for the unaccounted-for counterfeit masks, as they may have been removed from normal storage areas and placed in a secondary location unknown to SS-SC staff.
- Union officials (NAPE, CUPE, RNUNL, AAHP, NLMA, PARNL) have been made aware of the issue and will be kept advised as the collection of counterfeit N95s continues.

- There are approximately 34,000 3M N95s currently in inventory that are safe to use, which will be circulated to facilities for distribution.
 - This quantity represents approximately a 30-day supply.
 - Regular replenishment of 3M N95 stock will continue to be received from established vendors authorized by 3M. (i.e., vendors contracted pre-COVID for the provision of products at "normal" usage rates).
 - There are also other brands of N95s in stock that may be identified as a suitable substitute with FIT testing, should it be required.
- SS-SC has notified Bergwater of the issue. Bergwater was surprised to hear this and contacted their supplier in China to have certification documents provided.

Analysis:

- SS-SC has acted quickly to remove the counterfeit products from inventory and to retrieve those distributed to health care facilities.
- SS-SC and OHS will be reviewing documentation regarding the N95s, and whether the item meets filtration standards and would be safe to use, once employees are FIT tested with the product.
- SS-SC will work with Bergwater to investigate how these items, which were inspected by SGS prior to shipment, were confirmed as an authentic 3M product.
- If all masks cannot be accounted for, as they may have already been used in providing care, there is a possible risk that staff may have been exposed to infectious materials, not just the COVID-19 virus. This is yet to be determined and remains under investigation.

Action Being Taken:

- Attempts to collect the remaining 180 masks will continue.
- SS-SC will continue to engage with HCS on status of collection of the remaining 180 counterfeit N95s.
- OHS staff will review any employees fit tested with this 3M 1860 model during the month of December. FIT testing will be repeated if the compromised mask had been used.
- RHA staff will be advised that if they have concerns they may have used one of the counterfeit masks, they are to contact their OHS department for further follow up.
- Communication officials within the RHAs will be kept up to date in the event of media inquiries.
- SS-SC will establish a process to improve monitoring for possible recalls and product warnings, to ensure quick action to remove unsafe products from inventory.

Prepared/Approved by: P. Barnes/A. Bridgeman/A. Doody/K. Stone
 Reviewed by: M. Bannister/ C. Blundon, Cabinet Secretariat
 Ministerial Approval: Pending

January 7, 2021