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COVID-19: Collection, Disinfection and Storage Processes for Single-Use N95 Filtering Facepiece Respirators

CENTRE D'EXPERTISE EN RETRAITEMENT DES DISPOSITIFS MÉDICAUX – INTERIM RECOMMENDATIONS

September 30, 2021 - Version 4.0. Changes are indicated in yellow

The elements covered are based on the latest information available at the time of writing. Given that the context of the COVID-19 pandemic and the authorizations issued by Health Canada for the new technologies for disinfecting N95 filtering facepiece respirators (FFRs) are evolving, the recommendations in this document are subject to change. Health care facilities must therefore verify that the technologies, at the time of their use, are still authorized by Health Canada under the Interim Order for COVID-19 (Health Canada, 2021a).

Foreword

This publication uses the term "disinfection" of single-use N95 filtering facepiece respirators (FFRs) (also referred to as N95 masks) to refer to the chemical or physical process that inactivates infectious agents. It should be noted that the various reference publications and documents on the subject consulted by the Centre d'expertise en retraitement des dispositifs médicaux (CERDM) use the terms "decontamination," "disinfection," or both. The CERDM has chosen the term "disinfection" to conform to the reprocessing nomenclature that is generally accepted in Canada (CSA Z314.18).

Context

At the start of the COVID-19 pandemic, the CERDM evaluated the available options for disinfecting used single-use N95 FFRs in the context of a possible shortage of respiratory protection devices in health care facilities (INSPQ, 2021a,b). This constitutes a solution of last resort to be applied in the case of an anticipated shortage[1] of N95 FFRs so as to be able to distribute them to workers during a real shortage[2] of N95 FFRs when all other strategies for addressing the shortage fail to suffice (INSPQ, 2021c). In fact, this solution is not consistent with guidelines of the regulatory authorities regarding the reprocessing of single-use medical devices (SUMDs). This process falls within the context of efforts to identify alternative and additional strategies that would provide the best possible protection for workers in the event of a shortage. Health care facilities must follow the guidelines of the ministère de la Santé et des Services sociaux (MSSS) to assess the status of an N95 FFR shortage. In addition, N95 FFRs may only be disinfected using a technology authorized by Health Canada (2021a) under the Interim Order for COVID-19, and in accordance with the manufacturers' instructions.

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1 Strategies to be applied in the event of an anticipated shortage, but while supplies are available (after verification with the procurement department and the Ministère de la Santé et des Services sociaux (MSSS)).

2 Strategies to be applied in the event of a known shortage (after verification with the procurement department and the MSSS).

Currently, Health Canada has authorized the following manufacturers' technologies for the disinfection of N95 FFRs under the Interim Order for COVID-19 (Health Canada, 2021a, INSPQ, 2021b):

- Low-temperature sterilizers: STERRAD 100S, STERRAD NX and STERRAD 100NX from the company ASP (2021), Sterizone/VP4 from the company Stryker (2020) and V-PRO 1Plus, V-PRO maX, V-PRO maX2, V-PRO S2 from the company Steris (2020a).
- High-temperature sterilizers (steam sterilizers): AMSCO 400 and Century Medium from the company Steris (2020b) and BRAVO 17V and BRAVO 21V from the company SciCan Ltd (2021).
- Hydrogen peroxide vaporizers (room disinfection devices): the BQ50, L4, PROTEQ and Q10 models from the company Bioquell (2020).
- Disinfection device combining several technologies (UVC, vaporized hydrogen peroxide and ozone): Clean Flow Health Care Mini from the company Clean Works Medical (Clean Works, 2020).
- The disinfection device combining UVC with microwaves, hydrogen peroxide and ozone: PureTech™ from the company Medera Technologies Inc. (PureTech™, 2021).[3]

Objectives

This document is intended for managers and clinical personnel involved in medical device reprocessing (MDR).

Its purpose is to describe the guidelines to be followed for the overall process of collecting, disinfecting and storing single-use N95 FFRs in order to:

- Ensure the safety of personnel.
- Ensure compliance with and implementation of infection prevention and control (IPC) measures associated with disinfection activities.
- Ensure compliance with the disinfection procedures for used N95 FFRs as per the manufacturer's instructions for the technologies chosen to perform the disinfection.
- Standardize the process for disinfecting used N95 FFRs.

Precautions to be considered

Special care must be taken when using technology for disinfecting N95 FFRs since the instructions provided by the companies can only be applied to certain models of N95 FFRs and the number of disinfection cycles authorized can vary from one technology to another. It is therefore important to follow the instructions specific to the equipment being used.

In addition, Health Canada has provided clarification regarding the disinfection of N95 FFRs and aerosol generating medical procedures (AGMPs). Indeed, it has been noted (Health Canada, 2021b) that disinfected N95 FFRs “can be used for AGMPs when: correctly fitted and used with other appropriate personal protective equipment (PPE).” However, Health Canada also specifies that N95 FFRs used during an AGMP cannot be disinfected for subsequent use; they must be discarded.

[3] The process recommended in this document does not apply to the PureTech™ technology. This technology allows for the disinfection of one N95 FFR at a time by the user with the help of a microwave oven. Therefore, it does not require the intervention of personnel from the medical device reprocessing department (MDRD).

With regard to the concept of a single wearer for an N95 FFR, manufacturers' instructions can vary (from highly recommended to required). The CERDM recommends following the instructions of the manufacturer of the technology used.

Responsibilities

The medical device reprocessing department (MDRD) is responsible for developing a disinfection procedure in accordance with the manufacturer's instructions for the technology used to perform disinfection of N95 FFRs and with the information provided in this document.

The IPC department collaborates on validation of the facility's procedures tied to the disinfection of N95 FFRs.

Abbreviations

AGMP	Aerosol generating medical procedure
CA	Collection Attendant
CERDM	Centre d'expertise en retraitement des dispositifs médicaux (a centre of expertise in medical device reprocessing)
DIN	Drug Identification Number
FDA	Food and Drug Administration
HCW	Health Care Worker
HS	Hydroalcoholic Solution
IPC	Infection Prevention and Control
MDR	Medical Device Reprocessing
MDRA	Medical Device Reprocessing Attendant
MDRD	Medical Device Reprocessing Department
N95 FFR	N95 Filtering Facepiece Respirator
PPE	Personal Protective Equipment
UV	Ultraviolet Irradiation

Recommended process

The recommended process for collecting, disinfecting and storing single-use N95 FFRs help ensure the quality and harmonization of practices. It is described below.

Health care worker

Donning the N95 FFR

- The health care worker (HCW) retrieves the new N95 FFR from the facility's designated storage location.

- Using a permanent marker (only a permanent, soft-tipped marker that has been validated for use with the chosen sterilization process should be used) (CSA, 2018), the HCW writes the necessary information on the front of the N95 FFR, including number of disinfection cycles, department or unit, first name and surname. This ensures that the disinfected FFR is returned to the right place and to the right HCW, as recommended in the manufacturer's instructions (see the Precautions to be considered section).
- The HCW carries out a summary inspection of their N95 FFR to confirm its integrity (e.g., no soiling or damage) before donning it.
- The HCW dons their N95 FFR in accordance with the established procedure to ensure a proper fit. If the fit check reveals that the fit is inadequate, the HCW should discard the N95 FFR and obtain a new one.
- The HCW uses their N95 FFR in accordance with the established guidelines for use.

Doffing the N95 FFR

- The HCW doffs their N95 FFR in accordance with the established guidelines.
- The HCW conducts an initial summary inspection of the N95 FFR and must discard any N95 FFR with visible soiling or damage, or that has been used during an AGMP, in a designated container.
- The HCW places their used N95 FFR in a brown paper bag, making sure that the brown bag is properly labelled with the full name of the HCW and the return location of the department/unit, if applicable.
- The HCW deposits their brown bag (side-by-side others) in a labelled transport container dedicated to the collection of used N95 FFRs, in a designated storage location in a soiled utility area. The HCW makes sure to leave the lid of the transport container open.
- The HCW performs hand hygiene in accordance with the established internal procedure using either soap and water or a hydroalcoholic solution (HS).

Collection attendant

- The collection attendant (CA) must put on clean gloves to carry out their task. The CA ensures the collection of all transport containers labelled "Used N95 FFRs." The CA must carry out an external disinfection of the transport container.
- The CA places the disinfected transport container on a transport cart dedicated to the transport of soiled material. The CA takes the cart to the dedicated room of the decontamination unit. Only gloves must be worn for this process. Warning: the requirements concerning the wearing of PPE for the various zones passed through must be respected and may necessitate the wearing of additional PPE (e.g., passage through a containment zone).
- The CA places the transport containers on the designated shelf in the dedicated decontamination room.
- The CA removes the gloves and performs hand hygiene using either soap and water or a HS.
- The CA records the requested information on the activity log sheet (name and contact number of the drop-off person, location of department/unit, name and number of the person to contact for pick-up).

Decontamination room for the storage, sorting and bagging of used N95 FFRs

- Ventilation requirements for the decontamination room dedicated to the storage, sorting and bagging of N95 FFRs are the same as for the decontamination room of the MDRD, i.e. a negative pressure, a minimum of 10 air changes per hour completely evacuated to the outside and a temperature maintained between 18 °C to 20 °C.
- If it is impossible to obtain a dedicated room for this purpose, these activities could be carried out in the decontamination room (soiled area) of the MDRD by providing a dedicated space.
- It is important to avoid any cross-contamination between the usual activities of the MDRD and the disinfection of the used N95 FFRs.

Medical device reprocessing attendant

N95 FFR reception/inspection

- The medical device reprocessing attendant (MDRA) acknowledges receipt of containers of used N95 FFRs in the activity log.
- The MDRA puts on their usual PPE (protective gown, gloves, procedural mask, eye protection, head and shoe covers).
- The MDRA retrieves the containers of used N95 FFRs while avoiding touching other surfaces to avoid environmental contamination.
- The MDRA transfers the brown bags containing the used N95 FFRs, grouped by location, to a cart and brings them to the dedicated decontamination room.
- The MDRA opens one brown bag at a time and takes out the N95 FFRs one at a time. They then check the name, location and the number of disinfection cycles indicated on the N95 FFR. If the maximum number of disinfections has been reached, the N95 FFR must be discarded in a designated container. **The number of authorized disinfection cycles is specified in the manufacturer's instructions for the technology used** (ASP, 2021; Steris, 2020a; Stryker, 2020; Bioquell, 2020; Clean Works, 2020; SciCan, 2021).
- The MDRA performs a second inspection of each N95 FFR to detect the presence of any anomalies. If damaged, soiled or damp, the N95 FFR must be discarded in a designated container.
- The MDRA disinfects the transport containers and surfaces with a low-level disinfectant authorized by Health Canada (DIN), with broad-spectrum virucidal action (Government of Canada, 2021).

Pre-processing drying time

- **Low-temperature sterilization technology:** a drying period of at least one hour before disinfection is recommended depending on the length of time between end of use and collection. Either of two options may be chosen:
  - The period between end of use and collection is more than one hour and the storage conditions are respected (N95 FFRs are placed in a brown bag and the bags are placed side by side in an open container), in which case the drying period is sufficient;
  - The period between end of use and collection is less than one hour, in which case it is recommended that there be a drying period of at least one hour following inspection of the N95 FFRs. Inspected N95 FFRs should be placed on a grid shelf for drying.

Disinfection of N95 FFRs

- The MDRA disinfects the used N95 FFRs by **strictly following the established procedure included in the manufacturer's instructions for the technology used** (ASP, 2021; Steris, 2020a; Stryker, 2020; Bioquell, 2020; Clean Works, 2020; SciCan, 2021).
- **Low or high-temperature sterilization technology:** the MDRA must comply with the following additional precautions (dedicated sterilizer, IPC measures and surface cleaning):
  - Place the N95 FFR and a chemical indicator in a sterilization pouch dedicated to the technology used, avoiding external contamination during handling. The plan should be to use the two-person technique (one MDRA places the used and inspected N95 FFR in the pouch while another MDRA holds the pouch with clean gloves and seals the pouch);
  - Place the bagged N95 FFRs in a container on a disinfected and covered transport cart;
  - Disinfect transport containers belonging to the units and work surfaces using a low-level disinfectant with broad-spectrum virucidal action (Government of Canada, 2021);
  - Remove PPE and perform hand hygiene using either soap and water or a HS;
  - Before entering the disinfection room where the sterilizer is located, perform hand hygiene (using either soap and water or a HS) and put on gloves;
  - Bring the transport cart containing the bagged N95 FFRs directly to the dedicated sterilizer in the MDRD to avoid cross-contamination of the environment;
  - Load the bagged N95 FFRs, select the recommended cycle and perform quality controls of the load in accordance with the sterilizer manufacturer's instructions;
  - Once loading is completed, the MDRA disinfects the cart and the surfaces they have touched, using a low-level disinfectant with broad-spectrum virucidal action (Government of Canada, 2021);
  - Remove gloves and perform hand hygiene using either soap and water or a HS.
- **Hydrogen peroxide room vaporizer (Bioquell devices):** the MDRA must take the following additional precautions (IPC measures, cleaning of surfaces and health and safety measures):
  - Place the inspected N95 FFRs face up on a disinfection cart (metallic grid), spaced well apart with a minimal point of contact, in accordance with the manufacturer's instructions;
  - Disinfect the transport containers belonging to the MDRD and the work surfaces with a low-level disinfectant with broad-spectrum virucidal action (Government of Canada, 2021);
  - Remove PPE and perform hand hygiene using either soap and water or a HS;
  - Cover the disinfection cart containing the inspected N95 FFRs and then bring it directly to the dedicated disinfection room;
  - Before entering the disinfection room where the Bioquell device is located, perform hand hygiene using either soap and water or a HS and don PPE;
  - Before starting the disinfection cycle, the MDRA ensures that the manufacturer's instructions for the positioning of the quality controls, the placement of the devices (generator and ventilation units) and the selection of the disinfection cycle are followed. Also ensure that the health and safety instructions for the use of the unit (in particular, sealing of the room’s door and ventilation outlets) are followed;
  - Remove PPE and perform hand hygiene using either soap and water or a HS;
  - Ensure that the disinfection cycle is initiated and completed in accordance with the manufacturer's instructions.

Quality controls

- The MDRA fills out the quality control log (date, time, load number, load content, quality control results associated with the technology used).
- The MDRA inspects the reprocessed N95 FFRs and must dispose of any N95 FFR with visible soiling, damage or moisture in a designated container.
- The MDRA ensures that the aeration time for the reprocessed N95 FFRs is respected.

Post-disinfection aeration time

- **Low-temperature sterilization technology:** an aeration period of 24 hours is recommended for N95 FFRs following the disinfection cycle, with the pouch closed. This recommendation is applicable to the instructions of the three low-temperature sterilizer companies (ASP, Steris, Stryker) based on the results of the study conducted by the Institut de recherche Robert-Sauvé en santé et en sécurité du travail (IRSST, 2020).

Storage of disinfected N95 FFRs

- **Low-temperature sterilization technology:** the MDRA deposits the reprocessed N95 FFR pouches in a new disinfected transport container, indicating the user's name and the return location on the outside of the transport container. They add new brown bags for the return of used N95 FFRs, and ensure that the transport container is properly closed. During storage, the container holding the N95 FFRs must remain open.
- **High-temperature sterilization technology (steam sterilizer):** the MDRA deposits the reprocessed N95 FFR pouches in a new disinfected transport container, indicating the user's name and the return location on the outside of the transport container. They add new brown bags for the return of used N95 FFRs, and ensure that the transport container is properly closed.
- **Hydrogen peroxide room vaporizer or technologies including UVC:** the MDRA deposits the reprocessed N95 FFRs in a new white paper bag, indicating the user's name and the return location on the outside of the white bag. They add new brown bags for the return of used N95 FFRs. They make sure the transport container is properly closed.
- The MDRA ensures distribution takes place in accordance with the established internal procedure.

> Note that designated storage areas must be provided for the storage of disinfected N95 FFR containers to protect them from all contamination, moisture and soiling.

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Dissemination

In accordance with your MDRD's procedures.

Record of modifications

Version	Date	Pages	Modifications
4.0	2021-09-30	1 1 2 2 2-4	▶ Clarifications made to the note of warning ▶ Clarifications made to the Context section ▶ Update of Health Canada approved technologies and equipment (addition of two manufacturers of disinfection devices) ▶ Clarifications made to the Precautions to be considered ▶ Health Canada recommendations concerning AGMPs to be taken into account
3.0	2020-12-07	1 2 1-2-5-6-7 2-5-6 1 to 10	▶ Clarifications made to the Context section ▶ Amendment of the considerations related to the notion of a single wearer, in the Precautions to be considered section ▶ Addition of high-temperature sterilization (steam sterilizer) ▶ Essential elements for the Hydrogen Peroxide Room Vaporizer (Bioquell devices) ▶ Harmonization of nomenclature (filtering facepiece respirators vs masks) throughout the document
2.3	2020-06-30		▶ Pre-processing drying time ▶ Post-disinfection aeration time
2.2	2020-05-29		▶ Definition of the term disinfection in the section entitled Foreword
2.1 (In French only)	2020-04-20		▶ Identification of N95 FFRs
2.0 (In French only)	2020-04-16		▶ Title modification (initially: La désinfection des masques de protection respiratoire N95 à usage unique – Lignes directrices intérimaires (in French only) ▶ Details of authorized technologies ▶ Precautions to be considered during the overall process ▶ Environmental requirements of the decontamination room ▶ Disinfection steps for N95 filtering facepiece respirators (FFRs)
1.0 (In French only)	2020-04-02		▶ Creation of the guidelines

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The French version, entitled *COVID-19 : Processus de collecte, de désinfection et d'entreposage des appareils de protection respiratoire N95 à usage unique* is also available on the website of the Institut national de santé publique du Québec at:
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