ELASTOMERIC HALF FACE MASK RESPIRATOR CLEANING AND DECONTAMINATING PROCEDURE

Summary of Changes

<table>
<thead>
<tr>
<th>BC Cancer</th>
<th>NEW</th>
<th>Previous</th>
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<tr>
<td></td>
<td>Elastomeric Half Face Mask Respirator</td>
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<td>Cleaning and Decontaminating Procedure</td>
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1. Introduction

1.1. Focus

Standardize the cleaning, decontaminating, and disinfecting of individually-assigned elastomeric half face mask respirators (EHFR) and the filter cartridges used with them. These procedures align with the NAPRA Model Standards for Pharmacy Compounding of Sterile Hazardous Drugs.

1.2. Health Organization Site Applicability

BC Cancer Regional Cancer Centre Pharmacies.

1.3. Practice Level

PHSA Safety and Prevention:
- Review these procedures
- Provide train-the-fit-tester training sessions

Pharmacy Professional Practice Leaders
- Provide respirators
- Provide respirator spare parts
- Provide filter cartridges
- Provide cleaning and decontaminating solutions and supplies
- Provide training on how to clean the EHFR

Pharmacy Personnel
- Follow donning, doffing, cleaning, decontaminating, and storage procedures

1.4. Definitions

Anteroom: A room equipped with two doors, with a system/procedures that allows only one door to be open at any given time, which allows passage or movement of people or things from one environment to the other, while keeping the two environments isolated from one another.

Casing: The plastic cover enclosing the chemical cartridge and particulate filter.

Cleaning: Removal of dirt, dust and other substances that may host microorganisms.

Clean Room: A room in which atmospheric properties are controlled. The room’s functional parameters are kept at specified levels. The room is designed to minimize the introduction, generation and retention of particles. The clean room is an ISO Class 7
environment. For hazardous compounding, the clean room has negative pressure relative to adjacent areas.

**Decontamination:** Transfer of a hazardous drug contaminant from a fixed surface to a disposable surface. The wipe is then contained and discarded as hazardous waste.

**Disinfectant:** A disinfecting agent, typically of a chemical nature, that can destroy microorganisms or other pathogens, but not necessarily bacterial or fungal spores. Refers to substances applied to inanimate objects.

**Disinfection:** Treatment that eliminates most of the pathogens present on an object or surface.

**Demarcation Line:** A line (real or virtual) that separates the anteroom into two sides (a “dirty” and “clean” side).

**Germicidal Disinfectant Detergent:** An agent that is EPA-registered as both a cleaning agent and a disinfectant.

**Personal Protective Equipment:** All garb and accessories, such as mask, gloves, gown, and safety goggles, that protect both the sterile preparation and the personnel. It enables compliance with the expected specification of a controlled environment and protects personnel from exposure to physical or chemical risks.

**Set-up Room:** A room within the controlled area (not the anteroom or clean room) in which activities related to parenteral compounding occur, including staging of components for compounding. Safety stations, compounding supplies, and a utility sink may be located in this room.

### 1.5. Abbreviations and Acronyms

**EHFR:** Elastomeric Half Face Mask Respirator  
**EPA:** Environmental Protection Agency  
**GDD:** Germicidal Disinfectant Detergent  
**L:** Litre  
**ISO:** International Standards Organization  
**mL:** millilitre  
**NAPRA:** National Association of Pharmacy Regulatory Authorities  
**pH:** power of Hydrogen  
**PHSA:** Provincial Health Services Authority  
**PPE:** Personal Protective Equipment  
**SOP:** Standard Operating Procedure
1.6. **Need to Know**

Pharmacy personnel must have completed the following:

- Training in cleaning, decontaminating, and storing of the EHFR and the filter cartridges
- Demonstrate competency in cleaning, decontaminating, and storing of the EHFR and the filter cartridges
- Demonstrate competency in donning and doffing garb and PPE worn in each room of the controlled area

1.7. **Equipment and Supplies**

- Non-sterile chemotherapy gloves
- Safety goggles and a face shield, to protect against splashes (for the monthly EHFR clean only)
- Isolation gown (for the daily EHFR clean) or chemotherapy gown (for the monthly EHFR clean)
- North 7700 Series Premium Silicone Half Mask (See Appendix 1)
- North N-Series Combination Gas and Vapour Cartridges- Defender Multi-Purpose (75SCP100L)

2. **Procedure**

2.1. **Steps and Rationale**

Assemble the following equipment:

For **DAILY cleaning and decontaminating of the EHFR:**

- Elastomeric half face mask respirator
- Surgical mask along with other PPE required to be worn on the clean side of the demarcation line in the anteroom
- Isolation gown
- Four pairs of non-sterile chemotherapy gloves
- Approved GDD that contains a decontaminating agent or ready-to-use wipes (determine contact time)
- Low-lint towels
- Three large sealable plastic bags
For MONTHLY cleaning and decontaminating of the EHFR:

- Elastomeric half face mask respirator
- Safety goggles
- Face shield
- Chemotherapy gown
- Four pairs of non-sterile chemotherapy gloves
- Approved GDD that contains a decontaminating agent or ready-to-use wipes (determine contact time)
- Approved dishwashing liquid with a pH of 8-9
- Soft bristle (not wire) brush
- One 8 L bucket or a plug for the utility sink drain
- Low-lint towels
- Time piece (seconds)
- Three large sealable plastic bags

To decontaminate and disinfect the EHFR DAILY after use, follow these steps:

1. Exit the clean room into the anteroom per site procedures.
2. Remove face shield, surgical mask, and safety goggles and doff the respirator according to the Elastomeric Half Face Mask Respirator Donning and Doffing SOP. Dispose of the surgical mask into a hazardous waste container; place the face shield, safety goggles and respirator onto low-lint towels.
3. Remove the inner pair of chemotherapy gloves and wash hands with soap and water. Don two new pairs of non-sterile chemotherapy gloves.
4. Don a surgical mask (if not already done) if decontaminating and disinfecting the EHFR on the clean side of the anteroom. Otherwise, bring the used face shield, used safety goggles and respirator into the set-up room to complete the remaining steps.
5. Disassemble the respirator. (See Appendix 2)
6. Using new wipes moistened with a GDD that contains a decontaminating agent, decontaminate:
   - safety goggles
   - face shield
   - the filter cartridge casing (exterior surfaces)
   - do not wash or blow air into the filter cartridges inside the casing; the cartridge and filter must NOT get wet or they will not work properly
   - interior and exterior surfaces of the facepiece mask
7. Place decontaminated items onto new low-lint towels to air dry.
8. Dispose of used wipes as hazardous waste.
9. Remove both pairs of gloves and discard in a hazardous waste container. Wash hands with soap and water and don two new pairs of chemotherapy gloves.
10. Using new wipes moistened with a GDD, disinfect:
   - safety goggles
   - face shield
   - the filter cartridge casing (exterior surfaces)
     - do not wash or blow air into the filter cartridges inside the casing; the cartridge and filter must NOT get wet or they will not work properly
   - interior and exterior surfaces of the facepiece mask
   - all respirator components
11. Ensure components remain wet for the necessary contact time for the disinfectant being used.
12. Place disinfected items onto new low-lint towels to air dry.
13. Dispose of used wipes as hazardous waste.
14. If skin irritation has been noticed after repeated respirator use, the headband(s) and mask piece components may be rinsed with distilled or sterile (not tap) water after disinfection.
15. Once dry, reassemble the respirator by putting all the components back together, except for the filter cartridges (See Appendix 3). Thoroughly inspect each component for damage. Replace any damaged components.
16. Store the individually-assigned respirator in a new sealable plastic bag labelled with your name.
17. Once dry, place the filter cartridges into a new sealable plastic bag. Place this bag into a second new sealable plastic bag together with the updated BC Cancer Elastomeric Half Face Mask Respirator Filter Cartridge Cumulative Use-Time Log according to the Elastomeric Half Face Mask Respirator Donning and Doffing SOP.
18. Once dry, store safety goggles and face shield per site procedures.
19. Dispose of the used low-lint towels as hazardous waste or place reusable low-lint towels with other laundry.
20. Exit the set-up room per site procedures.
21. Document the respirator decontaminating/disinfecting per site procedures.
In addition to daily decontamination and disinfection, the EHFR must be decontaminated and disinfected MONTHLY, following these steps:

1. Exit the clean room into the anteroom per site procedures.
2. Remove face shield, surgical mask, and safety goggles and doff the respirator according to the Elastomeric Half Face Mask Respirator Donning and Doffing SOP. Dispose of the surgical mask into a hazardous waste container; place the face shield, safety goggles and respirator onto low-lint towels.
3. Remove the inner pair of chemotherapy gloves and wash hands with soap and water.
4. Don PPE appropriate for working in the set-up room.
5. Exit the anteroom into the set-up room. Bring the used face shield, used safety goggles and respirator into the set-up room.
6. Don clean safety goggles and a clean face shield.
7. Fill one 8 L bucket or the utility sink with 4 L of warm (not hot) tap water and add approximately 30 mL dishwashing liquid into the 4 L of water.
8. Disassemble the respirator. (See Appendix 2)
9. Using new wipes moistened with a GDD that contains a decontaminating agent, decontaminate the casing (exterior surfaces) of the filter cartridges and place onto a new low-lint towel. Do NOT immerse the filter cartridges into the water; do not wash or blow air into the filter cartridges. The cartridge and filter inside the casing must NOT get wet or they will not work properly.
10. Immerse the respirator and components (including headband with cradle suspension system), and the face shield and safety goggles that were worn in the clean room into the bucket or sink of detergent water. Time the immersion for two minutes.
11. Dispose of the used low-lint towels as hazardous waste or place reusable low-lint towels with other laundry. Lay out new low-lint towels.
12. After soaking for two minutes, decontaminate the respirator, components, face shield and safety goggles using a soft bristle brush, taking care not to damage the valves.
13. Rinse the items thoroughly with warm running tap water in the utility sink to ensure no residue remains. Allow excess water to drip off. Rinse the soft bristle brush in the same way.
14. Place the decontaminated items onto the new low-lint towels. Use additional clean low-lint towels to manually dry the items.
15. Exit the set-up room into the gowning room. Remove both pairs of gloves and discard into a hazardous waste container. Wash hands with soap and water and don two new pairs of non-sterile chemotherapy gloves.
Do NOT use the utility sink in the set-up room to wash hands.
Do NOT remove any other personal protective equipment at this time.
16. Don two new pairs of non-sterile chemotherapy gloves.
17. Return to the set-up room.
18. Using new wipes moistened with a GDD, disinfect
   o safety goggles that were worn in the clean room
   o face shield that was worn in the clean room
   o the filter cartridge casing (exterior surfaces)
     ▪ do not wash or blow air into the filter cartridges; the cartridge and
       filter inside the casing must NOT get wet or they will not work
       properly
   o the interior and exterior surfaces of the respirator
   o all respirator components
19. Ensure components remain wet for the necessary contact time for the
    disinfectant being used.
20. Place disinfected items onto new low-lint towels to air dry.
21. Dispose of used wipes as hazardous waste.
22. Once dry, store the items per steps 14-18 in the section To decontaminate and
    disinfect the EHFR DAILY after use, above.
23. Drain the water in the utility sink or empty the bucket into the utility sink.
24. Decontaminate the utility sink (and the bucket if used) using new wipes
    moistened with a GDD that contains a decontaminating agent. Rinse the utility
    sink (and bucket if used) with tap water. Dry and store the bucket.
25. Remove and disinfect the safety goggles and face shield worn when
    decontaminating the equipment worn in the clean room using a wipe moistened
    with a GDD agent. Store per site procedures.
26. Exit the set-up room per site procedures.
27. Document the respirator decontaminating/disinfecting per site procedures.

2.2. Documentation

Cleaning of the Elastomeric Half Face Mask Respirator must be documented per site-
specific procedures.
3. **Related Documents and References**

3.1. **Related Documents**

The following documents are related to this Standard Operating Procedure:

- Elastomeric Half Face Mask Respirator Donning and Doffing Standard Operating Procedure
- **BC Cancer Pharmacy Practice Standards for Hazardous Drugs Manual**
- **BC Cancer’s NAPRA Implementation Committee Presentation: Respirators**
- LearningHub Course: **NHA - WHS - Chemical Cartridge Respirator use in Pharmacy**; Course Code: 23870
  - This course covers use of elastomeric half face mask respirators and filter cartridges as well as cleaning, decontaminating and storing. It also demonstrates how to properly don and doff the respirator and conduct an inspection.
  - When the information provided in the course differs from this SOP, staff is expected to follow the steps as outlined in this SOP.
    - Note the respirator must be disassembled, cleaned and decontaminated, and then disinfected daily using a GDD that contains a decontaminating agent in two separate steps.
    - Note the respirator must be disassembled, cleaned and decontaminated, and then disinfected at least once a month using dishwashing liquid with a pH of 8-9 and water followed by a GDD.

3.2. **References**

3. Canadian Standards Association. (2018). **Selection, use, and care of respirators (-18th ed.).** Toronto, Ontario: Canadian Standards Association Group. Retrieved from [https://www.csagroup.org/store/product/CAN%25100CSA-Z94.4-18/?gclid=EAIaIQobChMIhKqQhKah8AlJbVbx-tBh1GTOHPEAYAiiAAEgK8SfD_BwE](https://www.csagroup.org/store/product/CAN%25100CSA-Z94.4-18/?gclid=EAIaIQobChMIhKqQhKah8AlJbVbx-tBh1GTOHPEAYAiiAAEgK8SfD_BwE)


8. Workplace Health & Safety FHA. (2020a). Cleaning and disinfection procedures for the use of reusable elastomeric half-facepiece respirators (EHFRs) during and between shifts. Unpublished manuscript.


4. Appendices

4.1. Appendix 1- Respirator Parts

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<th>Ref No.</th>
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<td>1a/1b</td>
<td>Basic facepiece mask</td>
<td>770011S, M, L</td>
</tr>
<tr>
<td>2</td>
<td>Cartridge connector</td>
<td>770016</td>
</tr>
<tr>
<td>3</td>
<td>Inhalation valve</td>
<td>770017</td>
</tr>
<tr>
<td>4</td>
<td>Exhalation valve seat</td>
<td>770019</td>
</tr>
<tr>
<td>5</td>
<td>Exhalation valve</td>
<td>770018</td>
</tr>
<tr>
<td>6</td>
<td>Exhalation valve guard</td>
<td>770020</td>
</tr>
<tr>
<td>7</td>
<td>Cradle suspension system</td>
<td>770092</td>
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4.2. Appendix 2- Disassembling the Respirator

To disassemble the respirator, detach the following pieces from the face piece and place onto a low-lint towel:

- Filter Cartridges - turn counter-clockwise (to the left) (not included in the image of the respirator parts shown in Appendix 1)
- Headband with cradle suspension system- pull the cradle system off of the tabs on the front of the mask
- Exhalation valve guard- pop off of the exhalation valve seat
- Exhalation valve and exhalation valve seat- push on the exhalation valve from the outside of the mask to remove the exhalation valve seat and exhalation valve in one piece. Careful not to damage the orange rubber exhalation valve. With your thumb and pointer finger, pinch the centre of the valve on the outside and gently pull the exhalation valve out of the exhalation valve seat.
- Cartridge connector and inhalation valve (one on each side)- push on the cartridge connector from the outside of the mask to remove the cartridge connector and inhalation valve in one piece. Careful not to damage the black rubber inhalation valve. With your thumb and pointer finger, gently pull the inhalation valve off of the tab on the back side of the cartridge connector.
4.3. Appendix 3- Reassembling the Respirator

To reassemble the respirator, attach the following pieces to the face piece:

- Exhalation valve and exhalation valve seat- from inside the mask, stretch the mask slightly while coaxing the exhalation valve seat into the front of the mask. The flat side of the exhalation valve seat faces inside the mask, the bevelled side of the exhalation valve seat faces outward. When inserting the orange rubber exhalation valve into the exhalation valve seat, slightly pull with great care on the long protrusion until the exhalation valve snaps into place. Ensure that the mask fits secure and uniform around the outside of the exhalation valve seat and that the exhalation valve seat is flush with the inside of the mask.

- Exhalation valve guard- snap the exhalation valve guard into place over the exhalation valve.

- Cartridge connector and inhalation valve (one on each side)- from inside the mask, stretch the mask slightly while coaxing the cartridge connector into the side of the mask. The flat side of the cartridge connector faces inside the mask, the threads on the cartridge connector face outward. When attaching the black rubber inhalation valve to the cartridge connector, gently stretch the inhalation valve over the tab. Ensure that the mask fits secure and uniform around the outside of the cartridge connector and that the cartridge connector is flush with the inside of the mask.

- Headband with cradle suspension system- Note the words “TOP” and “THIS SIDE OUT” on the cradle suspension system. This is the direction the cradle suspension system will be attached to the mask. Push the two holes on the front of the cradle suspension system onto the two silicone tabs on the front of the mask. The strap with the words “TOP” and “THIS SIDE OUT” attach to the tab furthest from the exhalation valve.

- Filter Cartridges (attached only during use of the respirator)- turn clockwise (to the right) until they are seated snugly against the cartridge connector; make sure the filter cartridges do not cross thread; do not over-tighten as this may crack the cartridge connectors or the filter cartridge casing.