



Provincial Health Services Authority

# ELASTOMERIC HALF FACE MASK RESPIRATOR DONNING AND DOFFING PROCEDURE

## Summary of Changes

	NEW	Previous
BC Cancer	Elastomeric Half Face Mask Respirator Donning & Doffing Procedure	

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# ELASTOMERIC HALF FACE MASK RESPIRATOR DONNING AND DOFFING PROCEDURE

## 1. Introduction

### 1.1. Focus

A standardized procedure for donning and doffing individually-assigned elastomeric half face mask respirators (EHFR). 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
- Support and assist fit-testing when needed

#### Pharmacy Professional Practice Leaders

- Provide respirators
- Provide respirator spare parts
- Provide filter cartridges
- Provide training on when and how to use an EHFR

#### Pharmacy Personnel

- Complete a respirator fit-test prior to first use of the respirator, and at minimum, annually thereafter.
  - Note that a hair cover, safety goggles, and face shield must be worn during fit-testing as they can affect the fit of the respirator.
  - If a surgical mask will be worn over the respirator due to the presence of an unfiltered exhalation valve, one must be worn during the fit test.
- Follow donning, doffing, cleaning, and storage procedures.
- Wear an EHFR with appropriate filter cartridges for the following activities:
  - Cleaning and decontaminating the Containment Primary Engineering Control (C-PEC)
  - Cleaning up a hazardous drug spill
  - Unpacking a shipment that contains a suspected or known damaged hazardous drug container
  - Using solution (e.g., cleaners, sporicidals) that could cause airway irritation

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- Complete the BC Cancer Elastomeric Half Face Mask Respirator Cartridge Cumulative Use-Time Log
  - Note that different filter cartridges will be worn during the daily cleaning and decontaminating of the Containment Primary Engineering Control (C-PEC) than are worn during the weekly decontamination of the C-PEC because of the different solutions used.
  - These filter cartridges will be stored in separate bins to avoid selection errors.

## 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.

**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.

**C-PEC:** A device that provides an ISO Class 5 environment for the exposure of critical sites during aseptic compounding and that is designed to minimize airborne contamination of hazardous products, to protect workers and the environment from exposure to hazardous drugs.

**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.

**Hand Hygiene:** All methods related to hand washing performed with soap and water, followed by a waterless alcohol-based hand rub with persistent activity.

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

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**Hazardous Drug:** A drug that exhibits at least one of the following characteristics in animals or humans:

1. carcinogenicity
2. teratogenicity or other developmental toxicity
3. reproductive toxicity
4. organ toxicity at low doses
5. genotoxicity

**OR** the drug:

1. has a structure and toxicity profile that mimics an existing drug previously determined hazardous by the above criteria
2. is or contains a living organism with the potential to cause infections in humans
3. has insufficient information to properly evaluate the characteristics of the drug but the drug is primarily used to treat cancer

**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.

## 1.5. Abbreviations and Acronyms

**C-PEC:** Containment Primary Engineering Control

**EHFR:** Elastomeric Half Face Mask Respirator

**HD:** Hazardous Drug

**IPA:** Isopropyl Alcohol

**ISO:** International Standards Organization

**NAPRA:** National Association of Pharmacy Regulatory Authorities

**PA:** Peracetic Acid

**PHSA:** Provincial Health Services Authority

**PPE:** Personal Protective Equipment

**sIPA:** sterile Isopropyl Alcohol

**SOP:** Standard Operating Procedure

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## 1.6. Need to Know

Pharmacy personnel must:

- demonstrate proper donning, including seal checks, and doffing procedures for the respirator.
- read the Elastomeric Half Face Mask Respirator Cleaning and Decontaminating SOP and demonstrate proper cleaning of the respirator.
- be clean shaven where the respirator seals with the face.

## 1.7. Equipment and Supplies

- Standard HD clean room PPE to be worn concurrently for all activities requiring use of an elastomeric respirator
- North 7700 Series Premium Silicone Half Mask (See Appendix 1)
- North N-Series Combination Gas and Vapour Cartridges- Defender Multi-Purpose (75SCP100L) (See Appendix 1)

## 2. Procedure

### 2.1. Steps and Rationale

**Donning a respirator on the dirty side of the demarcation line in the anteroom prior to entering the clean room**

1. On the dirty side of the demarcation line, when it comes time in the usual course of procedures to don respiratory PPE, don the respirator. Don a surgical mask over the respirator. (See Appendix 2)
2. While donning two pairs of shoe covers, cross over the demarcation line to the clean side of the anteroom. Perform hand hygiene and continue donning remaining garb and PPE, including safety goggles and a face shield per site procedures.
3. Enter the clean room per site procedures.

**Donning a respirator on the clean side of the anteroom after working in the clean room**

1. On the clean side of the demarcation line, when it comes time in the usual course of procedures to don respiratory PPE:
  - a. Remove inner gloves and dispose into hazardous waste.
  - b. Wash hands with soap and water (NOT alcohol-based hand rub) and don one pair of non-sterile chemotherapy gloves.

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- c. Don the respirator and surgical mask. (See Appendix 2)
2. Remove gloves and perform hand hygiene. Continue donning remaining garb and PPE, including safety goggles and a face shield per site procedures.
3. Enter the clean room per site procedures.

## Donning a respirator to clean up a hazardous drug spill

1. When it comes time in the usual course of donning PPE to don a respirator, don the respirator (See Appendix 2).
  - When responding to a spill outside of the clean room and anteroom, it is not necessary to don a surgical mask over the respirator.
  - When responding to a spill inside the clean room or anteroom, don a surgical mask over the respirator.
2. Clean up the hazardous drug spill per site procedures.

## Doffing a Respirator in the anteroom

1. Exit the clean room per site procedures.
2. In the anteroom, on the clean side of the demarcation line, lay out low-lint towels on a horizontal surface.
3. Remove face shield, surgical mask, and safety goggles. Dispose of the surgical mask in hazardous waste; place the safety goggles and the face shield onto the low-lint towel until ready to clean them.
4. Doff the respirator (see Appendix 3) and place onto the same low-lint towel the uncleaned face shield and safety goggles are on.
5. Remove inner chemotherapy gloves and dispose in hazardous waste.
6. Wash hands with soap and water (NOT alcohol-based hand rub) immediately after removal of inner gloves and dry using a low-lint towel.
7. Don a surgical mask.
8. Don two pairs of non-sterile chemotherapy gloves.
9. Lay out at least one new low-lint towel to place the decontaminated safety goggles, face shield, and respirator and components onto.
10. Decontaminate the respirator according to the Elastomeric Half Face Mask Respirator Cleaning and Decontaminating Standard Operating Procedure and place onto the new low-lint towels.
11. Decontaminate the face shield and safety goggles and place onto the new low-lint towels.
12. Remove outer pair of chemotherapy gloves.

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13. Record the use-time on the cartridge log and update the cumulative cartridge use-time (See Appendix 4: BC Cancer Elastomeric Half Face Mask Respirator Cartridge Cumulative Use-Time Log).
14. Once dry, place the cartridges together into a new sealable plastic bag. Then place this bag into a second sealable plastic bag together with the cartridge log.
15. Once dry, place the individually-assigned respirator into a new sealable plastic bag. Write your name on the bag.
16. Discard the low-lint towels into hazardous waste.
17. Store the individually-assigned respirator in its sealed bag that has been labelled with the user's name in the designated storage location.
18. Store the cartridges with their individual log in the designated storage location for future use. If the in-use time limit has been reached, dispose of the cartridges and start a new log sheet, assigning and recording a sequential cartridge number. Then file the old cartridge log.
19. Doff inner pair of chemotherapy gloves and discard into hazardous waste.
20. Wash hands with soap and water (NOT alcohol-based hand rub) and dry using a low-lint towel.
21. Leave the anteroom observing all usual procedures or don appropriate PPE to re-enter the clean room.

## **Doffing a Respirator after cleaning up a hazardous drug spill**

1. When it comes time in the usual course of doffing personal protective equipment to doff a respirator, doff the respirator (See Appendix 3).
2. Dispose of the used filter cartridges with other hazardous waste generated during the spill cleanup as hazardous waste.
3. Clean the respirator per the steps outlined in the monthly decontamination and disinfection section of the Elastomeric Half Face Mask Respirator Cleaning and Decontaminating Standard Operating Procedure.

## **2.2. Documentation**

BC Cancer Elastomeric Half Face Mask Respirator Cartridge Cumulative Use-Time Log (Appendix 4) must be completed every time the respirator is worn.

- Note that different filter cartridges will be worn during the daily decontaminating and disinfecting of the Containment Primary Engineering Control (C-PEC) than is worn during the weekly decontaminating and disinfecting of the C-PEC because of the different solutions used.

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## 3. Related Documents and References

### 3.1. Related Documents

The following documents are related to this Standard Operating Procedure:

- Elastomeric Half Face Mask Respirator Cleaning and Decontaminating 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 and storing. It also demonstrates how to properly don and doff the respirator and conduct an inspection.

### 3.2. References

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## 4. Appendices

### 4.1. Appendix 1- Respirator Parts

Ref No.	Replacement part name	Replacement part number	
1a/1b	Basic facepiece mask	770011S, M, L	
2	Cartridge connector	770016	
3	Inhalation valve	770017	
4	Exhalation valve seat	770019	
5	Exhalation valve	770018	
6	Exhalation valve guard	770020	
7	Cradle suspension system	770092	

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## 4.2. Appendix 2- Donning a Respirator

1. Remove the individually-assigned respirator from its storage bag or the appropriate-sized respirator from the hazardous drug spill kit.
2. Remove one pair of cartridges from their storage bag.
  - Select either the PA-labelled or IPA-labelled cartridges depending on the work to be performed. Select PA-labelled cartridges whenever work will include use of peracetic acid containing solutions (with or without the use of sIPA). Select IPA-labelled cartridges when work will **not** include use of peracetic acid containing solutions.
3. Dispose of the used storage bags into hazardous waste.
4. Inspect the respirator components and cartridges for damage and integrity:
  - a. Check that the straps still have elasticity.
  - b. Check the valves for signs of damage and that they are properly seated, lying flat on the valve seat.
  - c. Check the mask for cracks and tears.
  - d. Check the facial seal edges for distortion or buckling.
  - e. Check the filter cartridges for damage.
  - f. Do not use a respirator or cartridges that appear damaged.
5. Check the enclosed cartridge log to ensure that the recorded total cartridge use-time remains within the specified acceptable limit. Confirm that sufficient time remains to complete current tasks. Cartridges will be numbered as follows: YYYY-Chemical-Log#-Sequential# e.g., the first pair of cartridges opened and recorded in the log in 2021 would be assigned the number 2021-IPA-1-1 (or 2021-PA-1-1). When a new pair of cartridges is required, a new log is created, and they would be assigned numbers 2021-IPA-2-1 (or 2021-PA-2-1). IPA = Isopropyl Alcohol; PA=Peracetic Acid (Peridox)
  - a. Cartridges worn when cleaning up a hazardous drug spill are discarded with other hazardous waste generated during the spill cleanup. Therefore, there is no applicable cartridge use-time log to review.
6. Attach the cartridges to the mask by turning them clockwise (to the right).
7. Don the respirator (over the hair cover) according to the following detailed instructions and as taught during fit testing:
  - a. Holding the mask in place with one hand, place chin inside the respirator mask's chin cup, and the top of the mask over the nose.
  - b. With the other hand, position the top strap around the back of the head by pulling it over the crown of the head. Ensure the hair cover remains in place and fully covers the hair.
  - c. Then attach the lower straps around the back of the neck.

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- d. Pull the mask away from your face and maneuver it to assure it's centred and comfortable.
  - e. Adjust straps as necessary for best fit and optimal visibility, beginning with the top strap. Avoid over-tightening the straps because this could distort the mask and may cause leakage between the mask-to-face seal.
8. Perform both a positive and negative pressure seal check
- a. Positive pressure seal check: exhale normally while covering the exhalation valve with the palm of one hand. If the mask bulges slightly and no air leaks between the face and the mask, an effective seal has been obtained.
  - b. Negative pressure seal check: inhale normally while covering the filter cartridge openings with the palms of both hands. Hold your breath for five seconds. If the mask collapses slightly and no air leaks between the face and the mask, an effective seal has been obtained.



**Positive Pressure Seal Check**



**Negative Pressure Seal Check**

- 9. If you detect any leaks, reset the mask and/or re-adjust the tension of the head straps. Note that sometimes the straps may need to be loosened. If adjustments have been made, repeat both pressure seal checks until an effective seal has been obtained.
- 10. If an effective seal cannot be obtained, do not use the respirator. Consult your supervisor about obtaining a replacement respirator or being refitted to a different size.
- 11. If breathing is difficult, the filter cartridges may need to be replaced (early) due to saturation or moisture.
- 12. Don a surgical mask over the respirator, centred on the exhalation valve.

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## 4.3. Appendix 3- Doffing a Respirator

1. Remove the surgical mask (if worn) from the respirator and discard into a hazardous waste container.
2. Detach the lower straps from around the back of the neck.
3. Holding the respirator in place with one hand, remove the top strap over the crown of the head.
4. Be sure to keep the hair cover in place; do not remove the hair cover.
5. Place the respirator onto a low-lint towel.
6. Remove filter cartridges from the mask by turning them counter-clockwise (to the left).

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## 4.4. Appendix 4- BC Cancer Elastomeric Half Face Mask Respirator Filter Cartridge Cumulative Use-time Log

Centre: \_\_\_\_\_

For use with North Defender Multi-Purpose (75SCP100L) Filter Cartridges

Date filter cartridges removed from packaging (DD/MM/YY): \_\_\_\_\_

Designated solution used with these filter cartridges (*circle one*): **sIPA** or **PA**

*If using for the twice daily decontamination and disinfection of the BSCs (sIPA use) designate as sIPA* (Isopropyl Alcohol).

*If using for the weekly decontamination and disinfection of the BSCs (PA and sIPA use) designate as PA* (Peracetic Acid [Peridox]).

Select filter cartridges labelled PA whenever work will include use of peracetic acid containing solutions or other sporicidals (with or without the use of sIPA). Select sIPA-labelled filter cartridges when work will not include use of peracetic acid containing solutions or other sporicidals.

Assigned Filter Cartridge Number (YYYY-Chemical-Log#-Sequential#): \_\_\_\_\_

e.g., 2021-sIPA-1-1 or 2021-PA-1-1

These filter cartridges must be disposed of into hazardous waste and replaced before the maximum use time of \_\_\_\_\_ minutes, six months of use, or when damage is known or suspected, whichever occurs first.

Enter the number of minutes from the information below, corresponding to the solutions to be used.

**Per PHSA Occupational Health and Safety Advisor's Recommendation:**

- **sIPA:** Change filter cartridges after no more than **6,756 min** (112.6 hours) of daily disinfection.
- **PA:** Change filter cartridges after no more than **270 min** (4.5 hours) of weekly decontamination.
- **Other solutions:** Other solutions may include (not an exhaustive list): Accelerated Hydrogen Peroxide (AHP) (e.g., Oxivir, Accel PREvention, Accel INTERvention), CaviCide, and count toward total wear time calculation (column E).

\*Estimated time factor: Enter 5 minutes for daily decontamination + disinfection; Enter 15 minutes for weekly decontamination + disinfection

A	B	C	D	E	F	G
Date	Pharmacy Staff Name	Number of BSCs decontaminated and disinfected in this session (if applicable)	*Estimated Time factor (min)	Amount of time (min) the solution(s) is / are used outside of the BSC (if applicable)	Total daily time (min) [Column (CxD)+E]	Total cumulative time (min) Refer to page 1 to confirm disposal time.

**ELASTOMERIC HALF FACE MASK RESPIRATOR DOWNING AND DOFFING PROCEDURE**

<b>A</b>	<b>B</b>	<b>C</b>	<b>D</b>	<b>E</b>	<b>F</b>	<b>G</b>
<b>Date</b>	<b>Pharmacy Staff Name</b>	<b>Number of BSCs decontaminated and disinfected in this session (if applicable)</b>	<b>*Estimated Time factor (min)</b>	<b>Amount of time (min) the solution(s) is / are used outside of the BSC (if applicable)</b>	<b>Total daily time (min) [Column (Cx D)+E]</b>	<b>Total cumulative time (min) Refer to page 1 to confirm disposal time.</b>

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