

## STANDARD OPERATING PROCEDURE

<b>Chapter:</b> Science System and Performance (SSP)	<b>SOP#:</b>
<b>Section:</b> Vaccine Storage and Handling	
<b>Subject:</b> NSHA: Product Recalls (Panorama)	
<b>Approved by:</b>	<b>Approval Date:</b>
<b>Applies To:</b> Public Health Staff	

### INTRODUCTION

Successful immunization programs are dependent upon proper handling and storage of biological products. Careful management of vaccine product recalls are critical as the manufacturer has determined that the product is potentially unsafe for the public.

The purpose of this standard operating procedure is to outline the process for product recalls, initiated by Panorama. Only the Inventory Provincial role has permissions for the Create Product recall functionality in Panorama.

### Product Recall

#### Provincial Biological Depot Pharmacy Practicing Assistant

1. The Biological Depot receives notification that product has been recalled.
2. The Biological Depot Pharmacy Practicing Assistant will select Process product recall in the Inventory Maintenance menu and create a product recall in Panorama ([hyperlink to user guide sheet](#)).

#### Provincial Biological Depot Immunization Coordinator

3. The Provincial Biological Depot Immunization Coordinator confirms the product recall from the manufacturer, specifically, date of notification, brand name, product description, lot #, expiry date, reason/problem for recall and company.

4. The Provincial Biological Depot Immunization Coordinator communicates the product recall to the DHW CDPC Consultant by email and initiates product recall from the Bio-depot and Zone Public Health.
5. The Provincial Biological Depot Immunization Coordinator communicates (email) the immediate product recall to all the Zone Bio-coordinators, including Zone Health Protection Managers (Appendix 1).

### **Zone Biological Coordinators**

6. The Zone Biological Coordinators will search and view the product recall in Panorama ([hyperlink to user guide sheet](#)).
7. The Zone Biological Coordinators will contact all holding point locations where the recalled products are located ([hyperlink to user guide sheet](#)).
8. The Zone Biological Coordinators will search for recall product active requisitions and the status of these requisition ([hyperlink to user guide sheet](#)).
9. The Zone Biological Coordinators pull all product identified in the product recall from their bio-depot to be returned to the Provincial Bio-depot.
10. The Zone Biological Coordinators communicate with service providers, transit points to return all product identified in the product recall.
11. The Zone Biological Coordinators receive returns from zone providers in Panorama (SOP Receiving Returns).
12. The Zone Biological Coordinator returns product to the Provincial Bio-depot (SOP Receiving Returns).

### **Provincial Biological Depot Pharmacy Practicing Assistant**

13. The Biological Depot Pharmacy Practicing Assistant removes all product identified in the product recall from the Provincial Bio-depot.

14. The Biological Depot Pharmacy Practicing Assistant receives products from the Zone Bio-coordinators (SOP Receiving Returns).
15. Vaccines are stored until SOP Vaccine Return to Supplier is initiated by the Bio-depot Pharmacy Practicing Assistant (SOP Return to Supplier).

## DEFINITIONS

<b>Biologicals Depot</b>	The vaccine storage facility located within Public Health (PH) housing vaccines for district and provincial distribution.
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## REFERENCES

Nova Scotia Department of Health and Wellness. (2017). *Nova Scotia immunization manual*. Retrieved from <http://novascotia.ca/dhw/cdpc/documents/Immunization-Manual.pdf>

Public Health Agency of Canada (2015). National Vaccine Storage and Handling Guidelines for Immunization Providers 2015. PHAC, Ottawa, ON.

Government of Canada Recalls and Alerts (2017) [http://www.healthykanadians.gc.ca/recall-alert-rappel-avis/search-recherche/simple?s=&plain\\_text=&f\\_mc=3&js\\_en=&page=5&f\\_mc=3&f\\_sc=73](http://www.healthykanadians.gc.ca/recall-alert-rappel-avis/search-recherche/simple?s=&plain_text=&f_mc=3&js_en=&page=5&f_mc=3&f_sc=73)

USA Food and Drug Administration (2017). Guidance for Industry: Product recalls, Including Removals and Corrections (2017). USA Food and Drug Administration located at <https://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129259.htm>

## HISTORY

<b>CURRENT VERSION</b>
<b>Prepared by:</b> Stacey Dunphy

16. Reviewed by: Version Jana Vickers

17. #: October 13 , 2017

**RESCINDED VERSIONS**

**SOP #:**

**Version #:**

**SOP Subject:**

**Approved by:**

**Date approved:**

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**Appendix 1 - Provincial Biological Depot**

**URGENT MEMORANDUM**

To: Health Protection Managers, Public Health/ Manager, Health Protection, Scientific & System Performance, Public Health / Biological Clerk Coordinators

From: Immunization Coordinator Provincial Biological Depot

Date:

RE: **NS Biological Depot Product Recall**

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**Background:**

Specific details regarding product recall using the format of Canada.gc.ca Product Recalls and Alerts Biologic Vaccine @ [http://www.healthycanadians.gc.ca/recall-alert-rappel-avis/search-recherche/simple?s=&plain\\_text=&f\\_mc=3&js\\_en=&page=5&f\\_mc=3&f\\_sc=73](http://www.healthycanadians.gc.ca/recall-alert-rappel-avis/search-recherche/simple?s=&plain_text=&f_mc=3&js_en=&page=5&f_mc=3&f_sc=73)

**Product Recall**

Date Notification	Brand Name	Product Description (lot number/expiration date)	Reason/Problem	Company

**Return Process to the Provincial Bio-depot**

- 1) Communication with Service Providers to return product to Zone Bio-depot.
- 2) Zone Bio-depot Coordinator returns product to Provincial Biological Depot.

Questions regarding product recall can be sent to the Immunization Coordinator.

Respectfully,

Nova Scotia Biological Depot Immunization Coordinator

Contact Information