

	Name of Activity: Repacking vaccines from their original packaging		
	Role Performing Activity: Saskatchewan Health Authority, Athabasca Health Authority, Northern Intertribal Health Authority, First Nations and Inuit Health Branch staff (overseen by a licensed healthcare professional)		
Policy and Work Standard	Location: Saskatchewan Health Authority, Athabasca Health Authority, Northern Intertribal Health Authority, First Nations and Inuit Health Branch Staff		Department: Public health
	Document Owner: Ministry of Health		Work Standard originated: MoH
	Date Prepared: January 2021	Last Revision: March 30, 2021	Date Approved: March 30, 2021

Summary: Repackaging of vaccines must be done by or under the supervision of a licensed healthcare professional. Non-licensed healthcare staff may acquire the skills and competency to repackage vaccine with off-site supervision by a licensed healthcare professional as outlined in this document.

Task Sequence	Task Definition
1.	<p>It is a Health Canada requirement that a licensed healthcare professional (HCP) (e.g., physician, registered pharmacist, registered nurse, licensed pharmacy technician, licensed practical nurse) complete or supervise the packing of vaccines into new packages (e.g., cardboard boxes, opaque or amber bags) from their original packages (written communication from Health Canada to the Ministry of Health, 2020-11-13, see Appendix A).</p> <p>When non-licensed healthcare staff are utilized to repackage vaccines, the Saskatchewan Health Authority, Athabasca Health Authority, First Nations Inuit Health Branch and Northern Intertribal Health Authority will appoint a licensed HCP to oversee the training of the non-licensed staff.</p> <p>Upon training and completion of a competency assessment, supervision of the non-licensed staff may be provided indirectly where the licensed HCP is off-site but available for consultation and guidance, as needed. See #3 below.</p> <p>Please note: Licensed HCP and non-licensed staff who are repackaging vaccines must also be competent in packing a vaccine cooler/container for transport which is not outlined in this work standard. Refer to local/organizational work standards and/or instructions from the shipping container manufacturer.</p>
2.	<p><u>Procedure for Repackaging Vaccines</u></p> <ol style="list-style-type: none"> 1. Confirm the number of doses/ vials required to be repackaged. 2. Remove the required number of vials from their original containers. 3. Place the vials directly into new packages (i.e. opaque amber bag¹) under the required storage and handling conditions as outlined in the work standards on the COVID-19 Immunization Manual website: <ul style="list-style-type: none"> • COVID-19 Vaccine Cold Chain Management <p>See “Vaccine Packing Considerations” in the following work standards:</p> <ul style="list-style-type: none"> • Transportation of Pfizer COVID-19 Vaccine in a Frozen or Thawed State • Transportation of Moderna COVID-19 Vaccine in a Frozen or Thawed State • Transportation of Fridge Stable COVID-19 Vaccines 4. Securely seal the new packages and place a vaccine-specific label on the new packaging. Write the number of doses the new package contains on the label.

Task Sequence	Task Definition
	<ul style="list-style-type: none"> • Labels are created by the Ministry of Health and can be found on the COVID-19 Immunization Manual website under “Vaccine Ordering and Packing”. The label includes the following information: <ul style="list-style-type: none"> ○ vaccine name; ○ number of vials/syringes and corresponding doses; and ○ a QR code/e-link to the product monograph. <p>5. Store the new packages under required storage conditions until they are ready to be shipped.</p> <p>¹ Opaque amber bags are available to order from the Saskatchewan Health Authority warehouse. The bags are reusable.</p>
3.	<p><u>Training Requirements</u></p> <p>Licensed and non-licensed staff must be educated on the storage and handling requirements of the available COVID-19 vaccine they will be repackaging.</p> <p>The licensed HCP must determine the non-licensed staff is competent in repackaging vaccines before transitioning to off-site supervision.</p> <ul style="list-style-type: none"> ○ Competency is met when all steps outlined under Procedure for Repackaging Vaccines are completed independently at least 3 times by the non-licensed staff (can be completed on the same day). A sample competency checklist is provided in Appendix B. <p>Following completion of the initial training, with each new brand of COVID-19 vaccine being repackaged at the distribution hub, staff must be trained on the storage and handling requirements for that specific vaccine and non-licensed staff must be observed at least 1 time by the licensed HCP.</p>

Appendix A

Health Canada communication to the Saskatchewan Ministry of Health 2020-11-13:

Thank you for contacting Health Canada, Regulatory Operations and Enforcement Branch (ROEB), Drug Establishment Licence unit (DELU) and for your follow up questions.

We understand that the Saskatchewan Ministry of Health proposes to have vaccine depot staff (non-professionals) work in a vaccine depot with a packing area. The staff will take a manufacturer's vaccine tray (or boxes of 10 vials) of vaccines, take single or several vials (depending on doses needed) from the tray (or boxes) and place the vials in an amber-coloured bag. The staff will also include a product monograph in the amber bag.

Health Canada believes that under normal circumstances, what is being proposed, would only be acceptable if done in a health care setting (i.e., a pharmacy, hospital), overseen by a medical professional (i.e. a pharmacist, physician etc.). With those controls in place, these activities would not require a drug establishment licence (DEL) and would be regulated under the provincial authority.

Health Canada is of the view that a DEL would not be required if the work you are proposing be done in the vaccine depot, is supervised by a licensed healthcare professional. The healthcare professional would assume responsibility for the oversight of the work being done and would ensure measures to ensure quality controls are in place to help minimize any risks involved. Quality control considerations for the proposed approach would include, but are not limited to ensuring the following:

- an amber bag is being used;
- the correct vaccine vial is placed in the amber bag;
- the correct number of vials are placed in the amber bag;
- the correct product monograph is being used; etc.

Appendix B- Sample Competency Checklist

Vaccine Repackaging Competency Checklist

This checklist is to be completed by a licensed healthcare professional while directly observing a non-licensed healthcare staff member completing COVID-19 vaccine repackaging.

Name of staff member being observed: _____

Name of observing healthcare professional and designation: _____

Site: _____

Indicate one of the following within the Observation columns:
 Step completed Step not completed

Step	Observation #1 Date:	Observation #2 Date:	Observation #3 Date:	Comments
1. Cold chain management and COVID-19 vaccine transportation work standards reviewed				
2. Confirm the number of doses/vials required to be repackaged.				
3. Remove the required number of vials from their original containers.				
4. Place the vials directly into new packages (i.e. opaque amber bag) as outlined in the work standards				
5. Securely seal the new packages and place a vaccine-specific label onto the new packaging, including indication of number of doses in the package.				
6. The newly prepared packages are stored under required storage conditions until they are ready to be shipped.				

Complete this section when the staff member has demonstrated competency in repackaging vaccines at least 3 times.

Date competency assessment completed: _____

Signature of supervising licensed Healthcare Professional: _____