Vaccine Incident Report and Vaccine Return Form
Instructions and Guidelines

Idaho Vaccines for Children (VFC) providers must report all state-supplied non-viable vaccines to the Idaho Immunization Program (IIP). The McKesson Vaccine Return Form and/or the Wasted Vaccine Form must be completed and submitted to the IIP within four weeks of vaccine loss. When vaccine becomes non-viable due to inappropriate storage and handling, a Temperature Incident Report must also be completed.

Most non-viable vaccines need to be returned to McKesson Specialty for federal excise tax credit; however, some non-viable vaccine may not be returned to McKesson Specialty. There are two types of non-viable vaccine loss: Vaccine Returns and Vaccine Wastage.

Vaccine Return (Expired or Spoiled Vaccine) = A McKesson Vaccine Return Form is used for non-viable vaccines that are returned to McKesson Specialty, such as expired vaccine or vaccines that have been compromised in a storage and handling (temperature) incident.

Vaccine Wastage (Wasted Vaccine) = A Wasted Vaccine Form is used for any non-viable vaccines that cannot be returned to McKesson Specialty. The following wasted vaccine products should not be returned to McKesson Specialty, and should be disposed of properly:

- Broken vial/syringe
- Vaccine drawn up into syringe but not administered
- Lost or unaccounted for vaccine
- Non-vaccine products (e.g. IG, HBIG, diluent)
- Open vial but all the doses have not been administered

Reporting Instructions

- Providers must report all instances of expired, spoiled, and wasted vaccines to the IIP.
- Providers must notify the IIP immediately if the vaccine is involved in a storage and handling incident.
  - Providers should contact the appropriate vaccine manufacturer for guidance on determining if vaccine is spoiled based on the parameters of the temperature incident.
  - Provider must complete the Temperature Incident Report for all vaccines lost due to improper storage & handling.
- Providers need to complete and submit forms for all vaccine returns, wastage, and incidents.
  - Completed forms must be submitted to the IIP within four weeks of the loss.
  - Forms may be faxed to (208) 334-4914 or emailed to IIP@dhw.idaho.gov.

McKesson Vaccine Return Form

The McKesson Vaccine Return Form must be completed for all non-viable vaccines for return to McKesson Specialty.

- Complete the contact information at the top of the form.
- Complete all the information for the non-viable vaccines to be returned to McKesson Specialty.
  - Number of Doses to be returned
  - Vaccine Lot Number
  - Vaccine National Drug Code (NDC) Number
  - Vaccine Manufacturer
  - Vaccine Expiration Date

- Reason the vaccine is being returned:
  1. Expired Vaccine: Any vaccine with an expiration date that has passed.
  2. Refrigerator / Freezer too warm: Any vaccine exposed to out-of-range high temperatures (refrigerator greater than 46°F; freezer greater than 5°F) and is deemed non-viable.
  3. Refrigerator / Freezer too cold: Any vaccine exposed to out-of-range low temperatures (refrigerator less than 35°F; freezer less than -58°F) and is deemed non-viable.
  4. Failure to Store Vaccine Properly upon Receipt: Any vaccine shipment received and not put into the refrigerator or freezer and the vaccine is deemed non-viable.
  5. Mechanical Failure: Failure of the vaccine storage equipment resulting in vaccine loss.
  6. Natural Disaster / Power Outage
  7. Other
  8. Recall: Any vaccine returned due to a vaccine recall

Example:

Vaccine Type	# Doses	Lot #	NDC #	Manufacturer	Expiration Date	Reason Returned*
PCV	18	F15975	00005-1971-02	Pfizer	01-04-2013	1

- Sign and date the form.
- Submit the completed form to the IIP for processing by either:
  - Fax: 208-334-4914
  - Email: IIP@dhw.idaho.gov

NOTE: The IIP will contact McKesson Specialty to request a return shipping label(s) be mailed to your office. Return labels should be received within 7-10 business days. Please notify the staff member in your office who receives the mail to watch for the label. The label is the size of a postcard (or half a sheet of paper) and is often mistaken for "junk mail".

- Account for the wasted vaccine in IRIS (see Accounting for Returned or Wasted Vaccines in IRIS).
- Place a copy of the McKesson Vaccine Return Form in the box with the non-viable vaccines listed.
- Place the McKesson Return Label on the box.
- Ship the non-viable vaccines back to McKesson.

Wasted Vaccine Form

The Wasted Vaccine Form must be completed for all non-viable vaccines that may not be returned to McKesson Specialty. Non-viable, non-returnable vaccine should be disposed of properly.

- Complete the contact information at the top of the form.
- Complete all the information for the non-viable vaccines wasted.
  - Number of Doses Disposed
  - Vaccine Lot Number
  - Vaccine National Drug Code (NDC) Number
  - Vaccine Manufacturer
  - Vaccine Expiration Date

- Reason the vaccine was wasted:
  1. Broken vial or syringe
  2. Vaccine drawn up but not administered
  3. Lost or unaccounted for vaccine
  4. Non-vaccine products (e.g. IG, HBIG, diluent)
  5. Open vial but all doses have not been administered
  6. Other – Specify

Example:

Vaccine Type	# Doses	Lot #	NDC #	Manufacturer	Expiration Date	Reason Wasted*
IPV	8	G46790	49281-0860-10	Sanofi	08/14/2013	5
MCV	1	M159753	49281-0589-05	Sanofi	02/15/2014	2

- Sign and Date the form.
- Submit the completed form to the IIP for processing by either:
  - Fax: 208-334-4914
  - Email: IIP@dhw.idaho.gov
- Properly dispose of the vaccine.
- Account for the wasted vaccine in IRIS (see Accounting for Returned or Wasted Vaccines in IRIS).

Accounting for Returned or Wasted Vaccines in IRIS

After the appropriate McKesson Vaccine Return Form, Temperature Incident Report, and/or the Wasted Vaccine Form has been completed and submitted to the IIP, vaccines must be accounted for in IRIS. The table below is guidance for the type of vaccine loss and what actions should be taken in IRIS.

How Vaccine Was Lost	What Happens to the Vaccine	Reason for Inventory Modification in IRIS
Expired Vaccine*	Return Vaccine	Take no action in IRIS
Vaccine Lost to inappropriate temperatures	Return Vaccine	Doses Wasted
Broken Vial or Syringe	Dispose of Vaccine	Doses Wasted
Vaccine drawn up but not administered	Dispose of Vaccine	Doses Wasted
Open Vial but all doses have not been administered	Dispose of Vaccine	Doses Wasted

*Expired vaccine becomes inactive in IRIS and doses on hand currently remain in Inventory.

How to Modify Inventory Quantities to Account for Lost Vaccine

1. Log in to IRIS.
2. Select your organization.
3. Under the Inventory section in the left hand column. Click on *manage inventory*, then the click the *Show Inventory* button.

Vaccine Incident Report and Vaccine Return Form
Instructions and Guidelines

4. After the inventory is displayed, check the select box of the Trade Name and Lot Number that was wasted or returned.

Select	Trade Name	Lot Number	Inv On Hand	Active	Public	Exp Date
☑	Adacel	9562AD	31	Y	Y	04/01/2014

5. Next, click the Modify Quantity button which opens the Manage Inventory Screen.

Manage Inventory

Save Changes to Quantity On Hand for Selected Sites.... Save

Return to the Previous Screen.... Cancel

Modify Quantity On Hand for Selected Site(s)

Trade Name	Lot Number	Inv On Hand	Action	Amount	Reason
Adacel	9562AD	31	Add		Receipt of Inventory

6. In the Action column use the dropdown arrow and select "Subtract", in the Amount column enter the number of doses to subtract, and finally in the Reason column use the dropdown arrow to select the reason for the inventory modification.

Manage Inventory

Save Changes to Quantity On Hand for Selected Sites.... Save

Return to the Previous Screen.... Cancel

Modify Quantity On Hand for Selected Site(s)

Trade Name	Lot Number	Inv On Hand	Action	Amount	Reason
Adacel	9562AD	31	Subtract	10	Receipt of Inventory

Receipt of Inventory
Anonymous Dose
Error Correction
Doses Returned
Doses Transferred
Doses Wasted

7. Finally, click the Save button.

Manage Inventory

Save Changes to Quantity On Hand for Selected Sites.... Save

Return to the Previous Screen.... Cancel

Modify Quantity On Hand for Selected Site(s)

Trade Name	Lot Number	Inv On Hand	Action	Amount	Reason
Adacel	9562AD	31	Subtract	10	Doses Wasted

Idaho Immunization Program
Phone: (208) 334-5931 or (800) 554-2922
Fax: (208) 334-4914
Email: IIP@dhw.idaho.gov