Washington State Department of HEALTH

CVP TRAINING SERIES

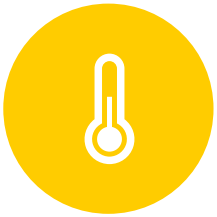
Office of Immunization
Childhood Vaccine Program
December 14, 2023

Topics Covered

REDCAP UPDATE

WHAT TO DO IN A POWER OUTAGE

EMERGENCY TRANSPORT GUIDELINES



REPORTING TEMPERATURE EXCURSIONS IN REDCAP

REDCap Update

Important Dates

December 1st, 2023

- Submit temp logs in REDCap
  - AVP only providers **REQUIRED**
  - Dually enrolled providers **REQUIRED**
  - CVP only providers **OPTIONAL**

January 1st,2024

- Submit temp logs in REDCap
  - All CVP and AVP providers will be **REQUIRED TO SUBMIT TEMPERATURE LOGS VIA REDCap**

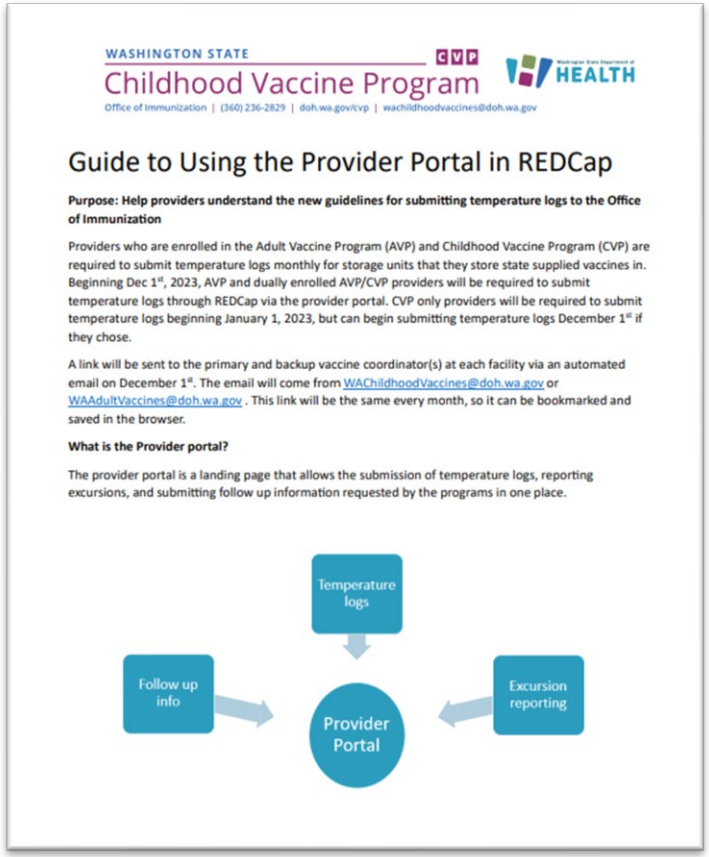
Submitting Temperature Logs

- Link will be sent 1st of the month
  - The primary and backup vaccine coordinator at each location will receive an automated email
  - Will come via WAchildhoodVaccines@doh.wa.gov or WAAdultVaccines@doh.wa.gov
  - Same link every month (bookmark it)
    - It will ask for facility PIN
- Answer questions, attach temp log and submit
  - Only submit one log for both AVP & CVP
  - Will still need to meet the same qualifications for temp logs
    - Temperature Reporting Guide
  - Follow up information will be submitted through the same link

REDCap Training Resources

- Training resources
  - Navigating Temperature Log Submission in REDCap Training Video and Power Point
  - Step-by-Step Guide to Using the Provider Portal in REDCap

- Weekly Office Hours at 12pm (see the CVP Training webpage for Zoom link)
  - Dec 20, 2023
  - Dec 27, 2023
  - Jan 3, 2024
  - Jan 10, 2024
  - Jan 17, 2024



WASHINGTON STATE CVP Childhood Vaccine Program

Office of Immunization | (360) 236-2829 | doh.wa.gov/cvp | wachildhoodvaccines@doh.wa.gov

Guide to Using the Provider Portal in REDCap

Purpose: Help providers understand the new guidelines for submitting temperature logs to the Office of Immunization

Providers who are enrolled in the Adult Vaccine Program (AVP) and Childhood Vaccine Program (CVP) are required to submit temperature logs monthly for storage units that they store state supplied vaccines in. Beginning Dec 1st, 2023, AVP and dually enrolled AVP/CVP providers will be required to submit temperature logs through REDCap via the provider portal. CVP only providers will be required to submit temperature logs beginning January 1, 2023, but can begin submitting temperature logs December 1st if they chose.

A link will be sent to the primary and backup vaccine coordinator(s) at each facility via an automated email on December 1st. The email will come from WAChildhoodVaccines@doh.wa.gov or WAAdultVaccines@doh.wa.gov . This link will be the same every month, so it can be bookmarked and saved in the browser.

What is the Provider portal?

The provider portal is a landing page that allows the submission of temperature logs, reporting excursions, and submitting follow up information requested by the programs in one place.

What to Do in a Power Outage

Plan Now for Inclement Weather

- Review your Vaccine Management Plan
- Train staff on emergency plans & the location of transport equipment
- Review the Vaccine Transport Guidelines
- Familiarize staff with the Temperature Excursion Guide
- Emergency transport does not require prior approval

Tool: Vaccine Management Plan

Vaccine Emergency Plan

Do not risk staff safety during an emergency. Use common sense when attempting to protect vaccines. Use the following guidance for safeguarding vaccines in the event of an emergency, such as mechanical failure, power outage, natural disaster, or human error.

In an emergency, contact the following people in the order listed:

Name	Role/Responsibility	Phone #	Alt Phone #	E-mail Address
1.				
2.				
3.				
4.				

Does the facility have a generator? ☐ Yes ☐ No
If so, where is it located?

It may be necessary to transport vaccines to an alternate storage location (e.g., a local hospital or another provider). Identify alternate location(s) that has vaccine storage units.

Alternate Facility	Address & City	Contact Name	Contact Information

Do you have a written agreement between you and your back-up facility? ☐ Yes ☐ No

Location of Back-up Digital Data Logger:

Location of Emergency Packing Supplies:

Tool: Vaccine Management Plan

Useful Emergency Numbers

Service	Name	Phone #	Alt Phone #	E-mail
Utility Company				
Building Maintenance				
Building Alarm Company				
Refrigerator/Freezer Alarm Company				
Refrigerator/Freezer Repair				

During an Emergency

Due to the risk to vaccines from improper packing and transporting, follow these instructions during an emergency to determine whether vaccines should be transported or sheltered in place.

Step	Description
1.	Do not open the unit.
2.	Place a "DO NOT OPEN" sign on vaccine storage unit(s) and leave door(s) shut to conserve cold air.
3.	Notify the emergency contacts.
4.	Note the time the outage started and document storage unit temperatures (CURRENT, MIN and MAX).
5.	Assess the cause of the power failure and estimate the time it will take to restore power.
6.	Take appropriate action. **In the event of appliance failure:** • Place vaccines in an approved backup storage unit with a program compliant data logger, or transport vaccines to the designated alternate storage facility. (Refer to Vaccine Transport section for instructions.) **In the event of thermometer failure:** • Place back up thermometer in storage unit. • Monitor and continually document temperatures until thermometer is reading temperatures within required ranges. **For power outages:** • Monitor storage unit temperatures. • If temperatures near out of range conditions, or for outages that extend beyond the current business day, transport vaccines to the alternate storage facility. (Refer to Vaccine Transport section for instructions.) • Monitor temperatures throughout transport and report any excursions. (Refer to Vaccine Temperature Excursion Guide)
7.	Once power has been restored, follow the steps listed in After an Emergency section.

Accessing Your Building After Hours

- Maintain a relationship with your facility's building manager and/or security staff.
- Ensure all staff members are familiar with emergency procedures, including after-hours roles and responsibilities.
- Include instructions for accessing your vaccine storage units when the building is closed, with a building map/diagram and locations of:
  - ✓ Spare batteries
  - ✓ Flashlights
  - ✓ Keys/Alarm codes
  - ✓ Locks
  - ✓ Circuit breakers
  - ✓ Emergency transport equipment and materials

During an Emergency

1. Do not open the unit
2. Place a "DO NOT OPEN" sign on the vaccine storage unit(s) and leave the door(s) shut to conserve cold air
3. Notify the emergency contacts on your Emergency Plan
4. Note the time the outage started and document storage unit temperatures (ROOM TEMP,CURRENT, MIN & MAX)
5. Assess the cause of the power failure and estimate the time it will take to restore power
6. Take appropriate action

Take Action!

For power outages:

- Monitor storage unit temperatures
- If temperatures near out-of-range conditions, or for outages that extend beyond the current business day, transport vaccines to the alternate storage facility
- Monitor temperatures throughout transport and report any excursions (refer to the Vaccine Temperature Excursion Guide)

Take Action!

In the event of appliance failure:

- Place vaccines in an approved storage unit with a program compliant data logger, or transport vaccines to the designated alternate storage facility

In the event of thermometer failure:

- Place back-up thermometer in storage unit
- Monitor and continually document temperatures until thermometer is reading temperatures within required ranges

After an Emergency

1. Verify power is restored and storage units are functioning properly
2. Once vaccine storage unit temperatures have stabilized, notify the emergency contacts identified on the Vaccine Management Plan
3. If vaccines were transported due to an emergency:
   a) Follow the same transportation procedures and transfer vaccine back to original storage unit
   b) If vaccines were kept within proper temperature during the power outage, notify supervisor that the vaccines may be used
4. If vaccines maintained required temperatures:
   a) Remove the "DO NOT OPEN" sign from the storage unit(s)
   b) Notify supervisor that the vaccines may be used

After an Emergency

- If vaccines were exposed to out-of-range temperatures:
  - Store vaccine under proper conditions as quickly as possible
  - Label affected vaccines "DO NOT USE"
  - Follow the Temperature Excursion Guide and contact vaccine manufacturers to determine whether vaccines are viable
  - Report the incident to the Childhood Vaccine Program via your REDCap portal as soon as possible or when you submit your monthly temperature logs

In case of a temperature excursion, call the manufacturers to determine vaccine viability		
AstraZeneca (Medimmune) 877-633-4411	Merck 800-672-6372	Pfizer 800-438-1985
GlaxoSmithKline 888-825-5249	Moderna 866-663-3762	Sanofi Pasteur 800-822-2463
MassBiologics (Grifols) 617-474-3000	Novavax 855-239-9174	Sequiris 855-358-8966

Knowledge Check #1

Emergency Transport Guidelines

Tool: Vaccine Transport Guidelines (CDC)

Packing Vaccines for Transport during Emergencies

Be ready BEFORE the emergency

Equipment failures, power outages, natural disasters—these and other emergency situations can compromise vaccine storage conditions and damage your vaccine supply. **It's critical to have an up-to-date emergency plan with steps you should take to protect your vaccine.** In any emergency event, activate your emergency plan immediately. Ideally, vaccine should be transported using a portable vaccine refrigerator or qualified pack-out. However, if these options are not available, you can follow the emergency packing procedures for refrigerated vaccines below:

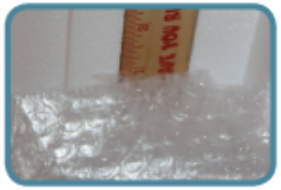
1 Gather the Supplies

Hard-sided coolers or Styrofoam™ vaccine shipping containers

- Coolers should be large enough for your location's typical supply of refrigerated vaccines.
- Can use original shipping boxes from manufacturers if available.
- Do NOT use soft-sided collapsible coolers.

Conditioned frozen water bottles

- Use 16.9 oz. bottles for medium/large coolers or 8 oz. bottles for small coolers (enough for 2 layers inside cooler).
- Do NOT reuse coolant packs from original vaccine shipping container, as they increase risk of freezing vaccines.
- Freeze water bottles (can help regulate the temperature in your freezer).
- Before use, you must condition the frozen water bottles. Put them in a sink filled with several inches of cool or lukewarm water until you see a layer of water forming near the surface of bottle. The bottle is properly conditioned if ice block inside spins freely when rotated in your hand (this normally takes less than 5 minutes.



Insulating material — You will need two of each layer

- **Insulating cushioning material** – Bubble wrap, packing foam, or Styrofoam™ for a layer above and below the vaccines, at least 1 in thick. Make sure it covers the cardboard completely. Do NOT use packing peanuts or other loose material that might shift during transport.
- **Corrugated cardboard** – Two pieces cut to fit interior dimensions of cooler(s) to be placed between insulating cushioning material and conditioned frozen water bottles.

Temperature monitoring device – Digital data logger (DDL) with buffered probe. Accuracy of +/-1°F (+/-0.5°C) with a current and valid certificate of calibration testing. Pre-chill buffered probe for at least 5 hours in refrigerator. Temperature monitoring device currently stored in refrigerator can be used, as long as there is a device to measure temperatures for any remaining vaccines.

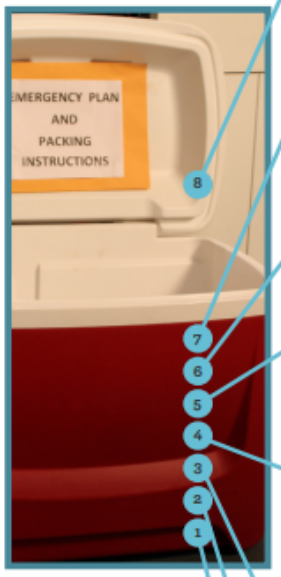
Tool: Vaccine Transport Guidelines (CDC)

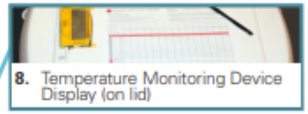
Packing Vaccines for Transport during Emergencies

2 Pack for Transport

Conditioning frozen water bottles (this normally takes less than 5 minutes)

- Put frozen water bottles in sink filled with several inches of cool or lukewarm water or under running tap water until you see a layer of water forming near surface of bottle.
- The bottle is properly conditioned if ice block inside spins freely when rotated in your hand.
- If ice "sticks," put bottle back in water for another minute.
- Dry each bottle.
- Line the bottom and top of cooler with a single layer of conditioned water bottles.
- Do NOT reuse coolant packs from original vaccine shipping container.

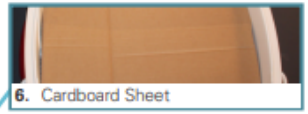



8. Temperature Monitoring Device Display (on lid)

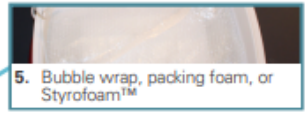
Close lid – Close the lid and attach DDL display and temperature log to the top of the lid.


7. Conditioned Water Bottles

Conditioned frozen water bottles – Fill the remaining space in the cooler with an additional layer of conditioned frozen water bottles.


6. Cardboard Sheet

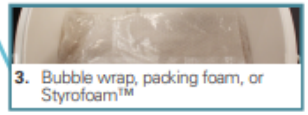
Insulating material – Another sheet of cardboard may be needed to support top layer of water bottles.


5. Bubble wrap, packing foam, or Styrofoam™

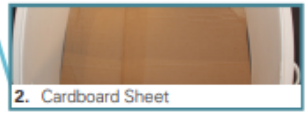
Insulating cushioning material – Cover vaccines with another 1 in. layer of bubble wrap, packing foam, or Styrofoam™


4. Vaccines, Diluents, and Temperature Monitoring Device Probe

Vaccines – Add remaining vaccines and diluents to cooler, covering DDL probe.
Temperature monitoring device – When cooler is halfway full, place DDL buffered probe in center of vaccines, but keep DDL display outside cooler until finished loading.
Vaccines – Stack boxes of vaccines and diluents on top of insulating material.


3. Bubble wrap, packing foam, or Styrofoam™

Insulating cushioning material – Place a layer of bubble wrap, packing foam, or Styrofoam™ on top (layer must be at least 1 in. thick and must cover cardboard completely).


2. Cardboard Sheet

Insulating material – Place 1 sheet of corrugated cardboard over water bottles to cover them completely.


1. Conditioned Water Bottles

Conditioned frozen water bottles – Line bottom of the cooler with a single layer of conditioned water bottles.

NOTE:
This pack-out can maintain appropriate temperatures for up to 8 hours, but the container should not be opened or closed repeatedly.

Vaccine Transport Guidelines

Why do you need cardboard, bubble wrap and conditioned water bottles?
Conditioned frozen water bottles and corrugated cardboard used along with one inch of insulating cushioning material such as bubble wrap keeps refrigerated vaccines at the right temperature and prevents them from freezing.

Reusing vaccine coolant packs from original vaccine shipping containers can freeze and damage refrigerated vaccines.

2023 Vaccine Transport Requirements

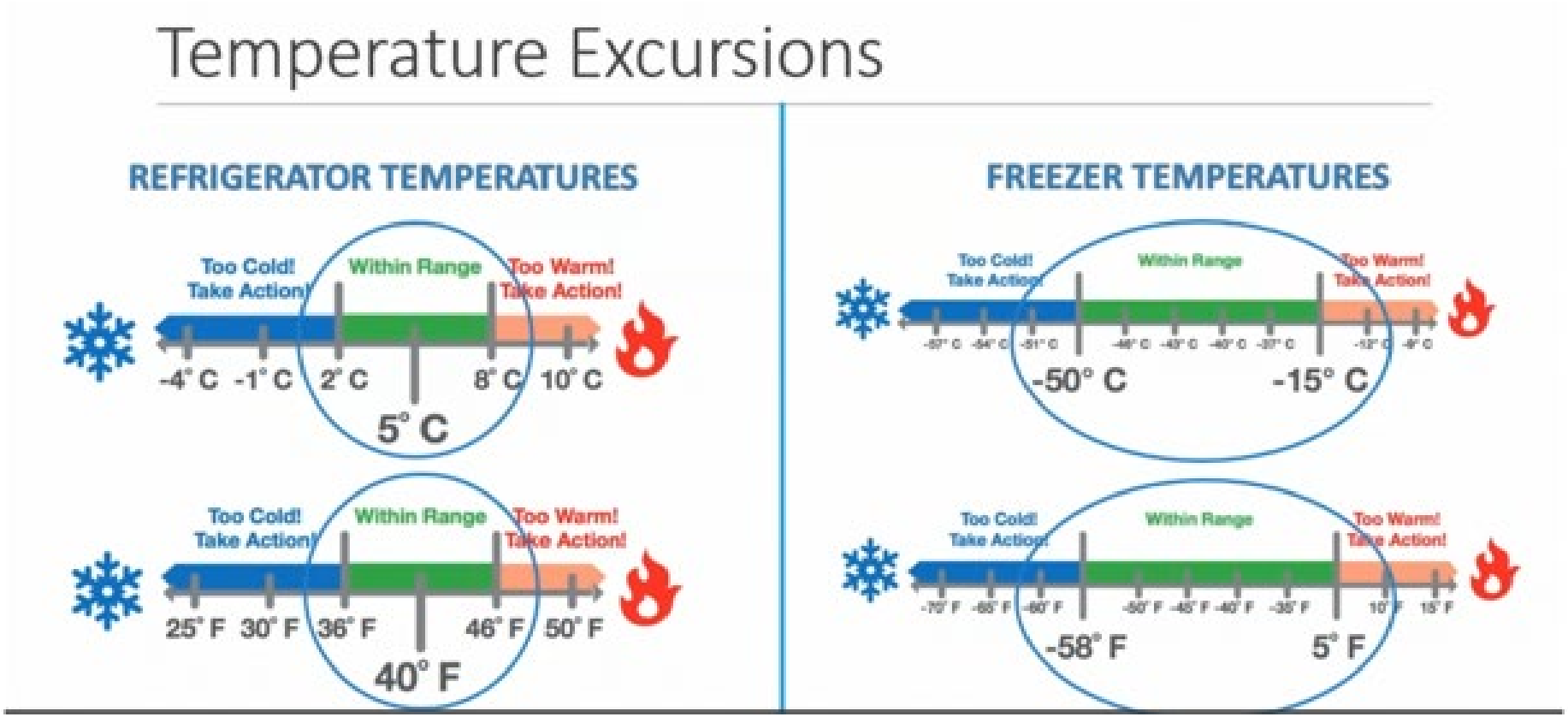
Vaccine Transfer/Transport Equipment				
Type of Unit	**Emergency Transport**	**Routine Transfer**	**Off-site Clinic**	**Clinic Move**
Portable Vaccine Refrigerator or Freezer	Yes	Yes	Yes	Yes
Qualified Container and Packout	Yes	Yes	Yes	Yes
Conditioned Water Bottle Transport System	Yes	Yes	No	Yes
Hard-sided cooler	Yes	Yes	No	Yes
Manufacturer's Original Shipping Container	Yes (Last resort only)	No	No	Yes (Last resort only)
Pre-approval Required	No*	Yes	Yes	Yes

*Transporting vaccine during an emergency (e.g.: power outage) does not require pre-approval

Knowledge Check #2

Reporting Temperature Excursions in REDCap

Temperature Excursions



Temperature Excursions Require Immediate Action!

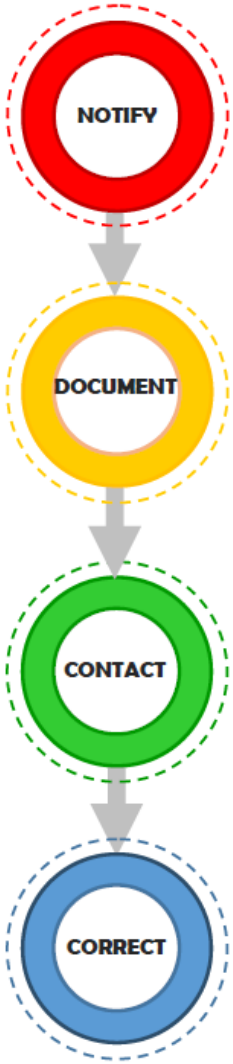
- In general, manufacturers analyze information about the magnitude of the temperature excursion to determine vaccine viability.
- It is helpful to have the following information handy:
  - Date, time, and name of person completing the report
  - Description of the event, storage unit temperature, inventory of vaccines affected
  - Determine the length of time the vaccine has been out of range by reviewing your digital data logger
  - Be sure to include any previous temp excursions

Tool: Vaccine Temperature Excursion Guide

WASHINGTON STATE CVP
Childhood Vaccine Program
Office of Immunization | (360) 236-2829 | doh.wa.gov/cvp | wachildhoodvaccines@doh.wa.gov

Washington State Department of HEALTH

Vaccine Temperature Excursion Guide



Notify the primary or backup vaccine coordinator immediately if you discover a temperature excursion.

Bag the affected vaccines and place a label on them saying "DO NOT USE." Do not discard these vaccines or remove them from the storage unit.

Document the details of the temperature excursion including the:

- Date, time, and name of person completing report, description of the event, storage unit temperature, inventory vaccines affected
- Determine the length of time the vaccine has been out of range including any previous temp excursions

After manufacturer determination:

- Note date and length of time out of range on vaccine boxes
- Document the excursion via your REDCap portal including manufacturer determination and/or case number(s)
- Submit the Vaccine Loss Log if loss is over $2500

Contact the vaccine manufacturers. Be prepared to provide documentation and data logger information. Follow manufacturer guidance based on viability of vaccines. Record and save any case numbers or PDFs/emails of stability information.
If manufacturer guidance is unclear or states that providers can use their discretion to continue to use the vaccine, you must contact the DOH Childhood Vaccine Program at WAChildhoodVaccines@doh.wa.gov. Providers do not have the authority to discard publicly purchased vaccines.

Manufacturer Contact Numbers (Click links for online tools where available)	
AstraZeneca (Medimmune)	877-633-4411
GlaxoSmithKline	888-825-5249
MassBiologics (Grifols)	617-474-3000
Merck	800-672-6372
Moderna	866-663-3762
Novavax	855-239-9174
Pfizer	800-438-1985
Sanofi Pasteur	800-822-2463
Seqirus	855-358-8966

Determine and address what caused the temperature issue. Check the basics, including the power supply, the unit door, and thermostat settings.

If the excursion was the result of a temperature fluctuation, follow guidance on adjusting the storage unit temperature to the correct range.

If the thermometer failed, implement your back-up thermometer. If the storage unit failed, implement your emergency plan.

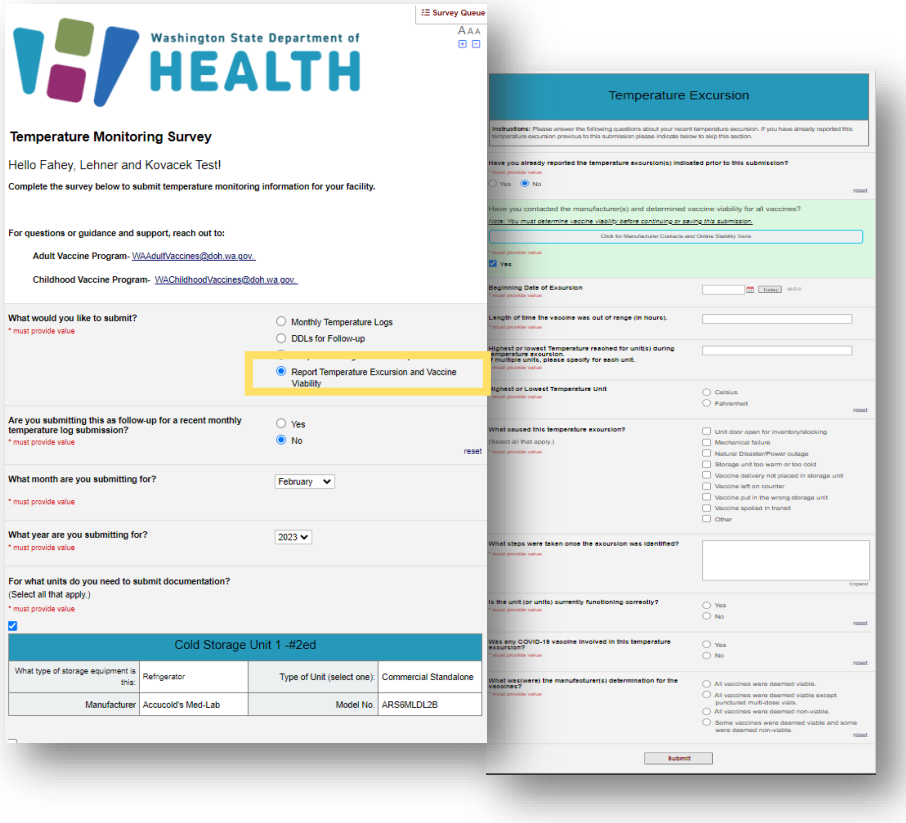
If vaccines were moved to another unit please provide 3 days stable temps in range before moving vaccines back into unit.

For people with disabilities, this document is available on request in other formats. To submit a request, please call 1-800-525-0127 (TDD/TTY 711).
DOH 348-708 January 2024

Reporting Excursions

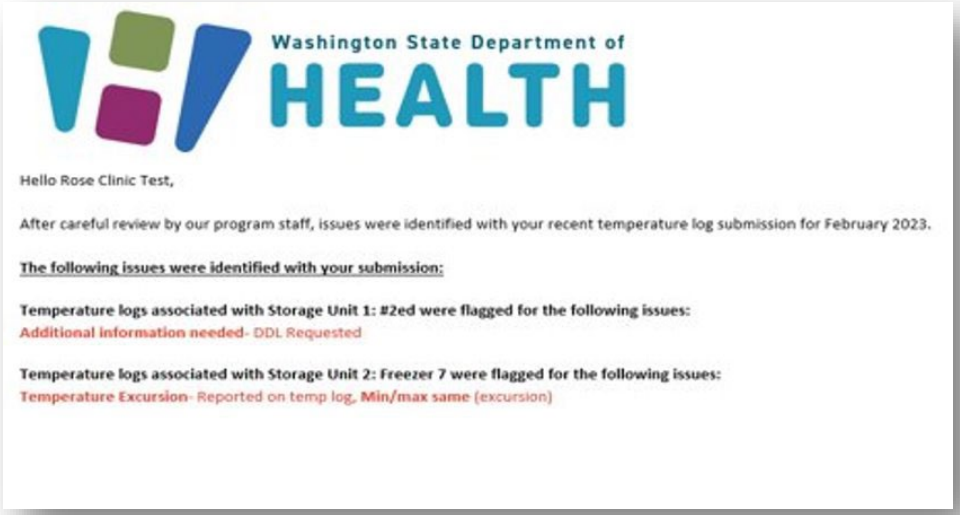
- Beginning January 1, all excursions will be reported through your REDCap portal
  - When they occur

    or
  - With monthly temp log submission
- Select Report Temperature Excursion and Vaccine viability
- Make sure you have the following:
  - Any viability information you received from the manufacturer
  - DDLs



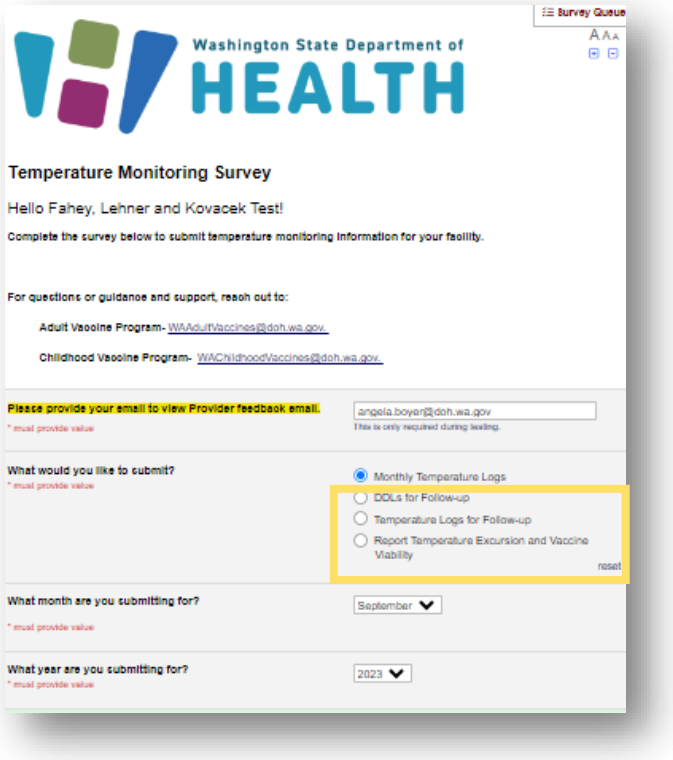
Submitting Follow Up Information

- A request may be sent for additional information
- Storage unit and issue found will be included
- Submit information through the same link



Submit Follow Up Information

- Select either DDLs for follow up or Temperature Logs for follow up
- If an excursion was not reported
- Respond to remaining questions



Tools and Resources

- Childhood Vaccine Program
- Vaccine Storage Unit Guide
- Vaccine Management Plan
- Vaccine Transport Guidelines
- Temperature Excursion Guide (post on storage unit)
- DOH Storage and Handling Webpage
- Navigating Temperature Log Submission in REDCap Training and Power Point
- Step-by-Step Guide to Using the Provider Portal in REDCap
- Childhood Vaccine Program Training

Questions?

Childhood Vaccine Program Main Contact Information
WAChildhoodVaccines@doh.wa.gov
Phone: (360)236-2829
Fax: (360)236-3811

To request this document in another format, call 1-800-525-0127. Deaf or hard of hearing customers, please call 711 (Washington Relay) or email doh.information@doh.wa.gov.

DOH 348-1015 December 2023