



Review of Temperature Excursion Protocol



HDOH VACCINES FOR CHILDREN (VFC) PROGRAM

February 13, 2024

Kealohi Corpus, Vaccine Supply Chain Quality Assurance Assessor



Housekeeping

Please ensure you are muted throughout the presentation unless you are speaking.

Reminder for QA Team:

Please monitor the chat for questions you may be able to answer.

Reminder to Attendees:

Today's session is being recorded. Slides and webinar recordings will be uploaded to: <https://health.hawaii.gov/docd/for-healthcare-providers/vaccination-resources/vaccines-for-children-program-vfc/>

To be added to the Hawaii VFC Program email list, please email your request to HawaiiVFC@doh.Hawaii.gov. In the subject line of the email, please write **EMAIL LIST**.



Questions?

- During today's webinar, please use the chat to ask your questions so the Hawaii VFC Program subject matter experts can respond directly.
- We will be answering your questions at the end of the presentation

Objectives

By the end of the presentation, providers should be able to:

- Correctly identify and respond to both fridge and freezer temperature excursions
- Understand the significance of each step in the excursion process
- Complete the temperature excursion process accurately and thoroughly in response to any out-of-range temperatures

What is a Temperature Excursion?

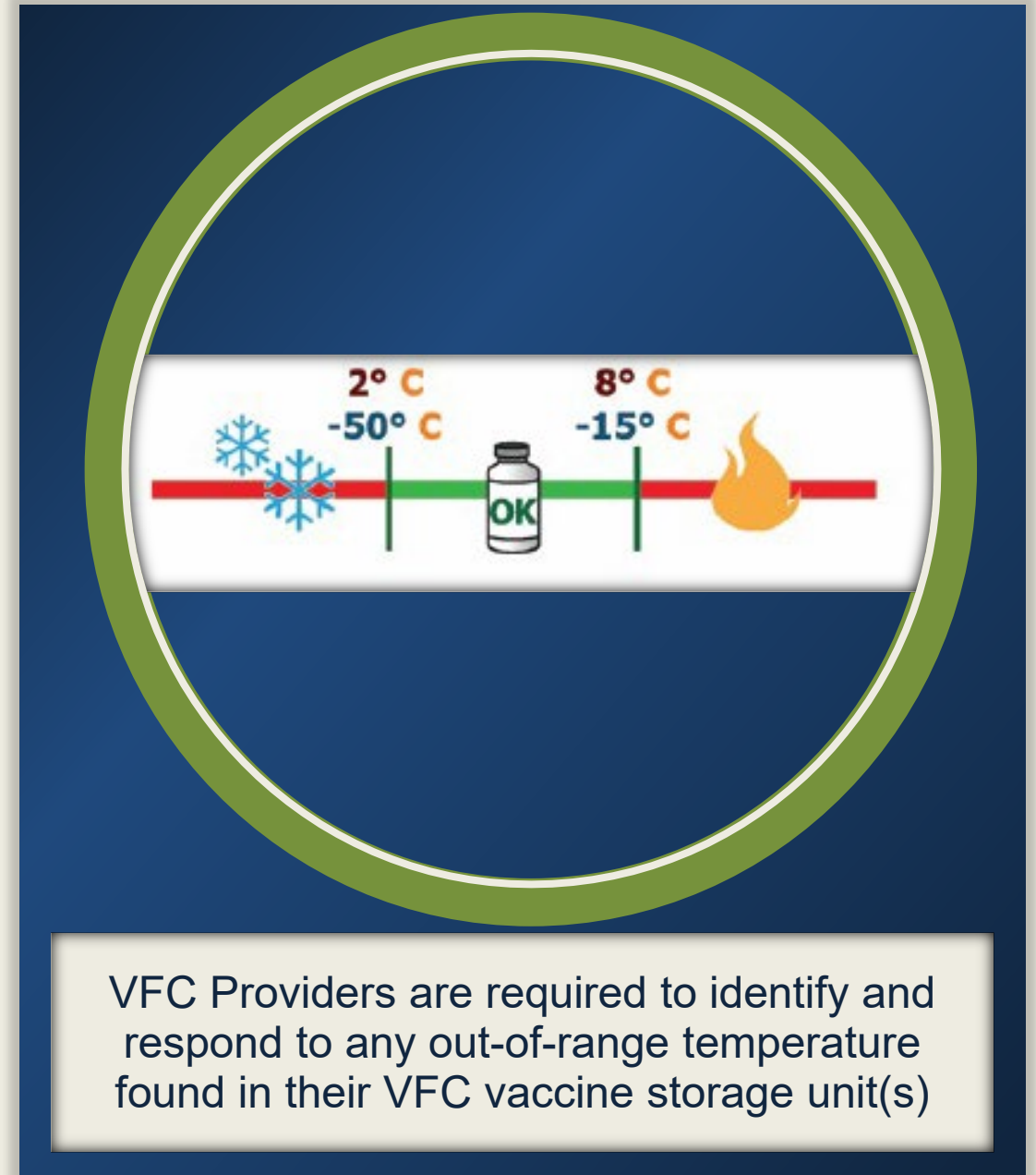


Temperature Excursion

- As defined in the CDC Vaccine Storage & Handling Toolkit: a temperature excursion is **any temperature reading** outside of the recommended ranges in the manufacturers' package insert.

CDC Vaccine Storage & Handling Toolkit

- Recommended temperature range by unit:
 - Refrigerator: 2°C – 8°C or 36°F-46°F**
 - Freezer: -50°C – -15°C or -58°F – +5°F**
 - Ultra-Cold: -90°C – -60°C or -130°F – -76°F**



VFC Providers are required to identify and respond to any out-of-range temperature found in their VFC vaccine storage unit(s)

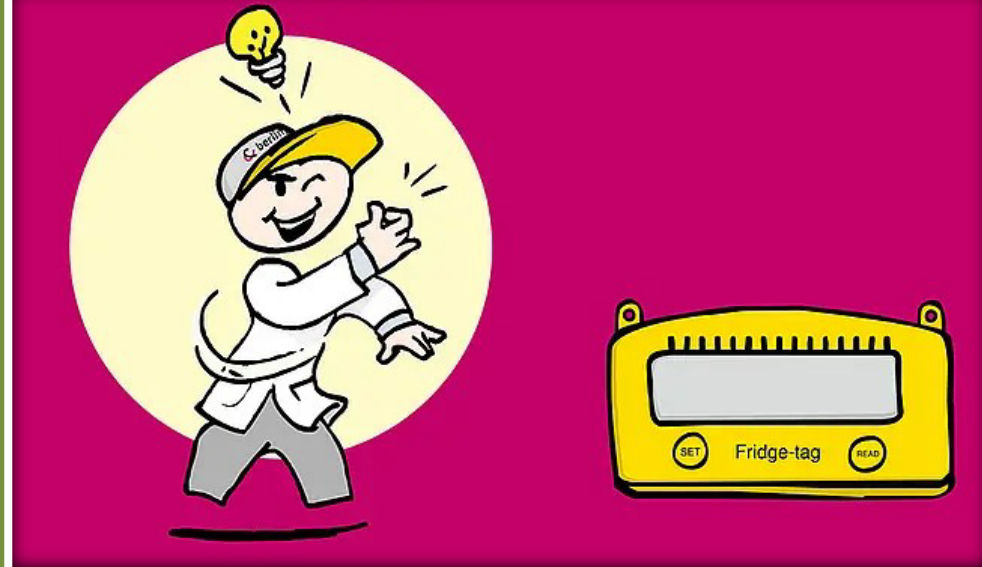
How to identify a temperature excursion

- Complete daily temperature monitor checks.
 - Check minimum & maximum temperatures – once per workday
 - Check current temperature – twice each workday
 - Document any out-of-range temperatures in the space indicated below and contact HDOH VFC QA Team

Danger! Temperatures below 2°C are too cold! Write any out-of-range temps

ACTION	Write any out-of-range temps (above 8°C or below 2°C) here:										
	Room Temperature										

- Check your DDL (digital data logger) data regularly.
 - Requirement: every two weeks – download & save*
- If you are unsure or not confident in identifying a temperature excursion, please contact the HDOH VFC Program: HawaiiVFC@doh.Hawaii.gov or 808-586-8300



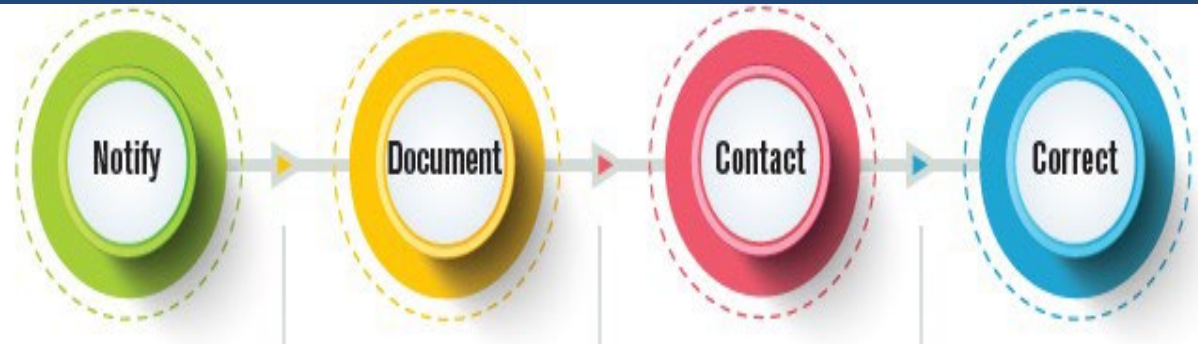
Please refer to our webinar on Temperature Logs for more info on DDLs, temperature logs, etc. here: [Hawaii VFC Program Temperature Log Review | Disease Outbreak Control Division](#)

Responding to Temperature Excursions



Excursion Protocol

1. Identify & Notify
2. Download and Evaluate details of event
3. Contact manufacturers and HDOH VFC QA Team



Identify & Notify

1. Immediately stop vaccinating with suspected vaccine. Separate vaccine and label **“DO NOT USE – AWAITING GUIDANCE”**
 - *If unit has not returned to appropriate temperature range, please move vaccine to back-up unit/emergency location as detailed in your facility’s Emergency Response Protocol*
2. Implement immediate corrective action, if possible (ex. shut the door if left open, resupply power, etc.)
3. Notify clinic VFC Primary/Back-up Coordinator(s) and/or supervisor

Download & Evaluate Details of Excursion Event

1. Download and review all DDL (digital data logger) data. DDL data refers, but is not limited, to:
 - Accuvax comprehensive reports
 - Sensoscientific Two-Point Monitoring data set
 - Berlinger FridgeTag data table & graphs
 - *If multiple excursions have occurred, manufacturers will utilize the cumulative exposure time/temperatures*
2. Determine the root cause of the temperature excursion(s) and document all the steps taken to address excursion event(s) in the **HDOH VFC Troubleshooting log** – See section 7: [Temperature Excursions of VFC Toolkit](#)
3. If unit has not returned to appropriate temperature range following the excursion, implement your Emergency Response Plan for transport to back up location/unit.
 - *See Section 8: [Vaccine Transport for more information on Emergency Transport protocols](#)*

Contact Manufacturers & HDOH VFC QA TEAM

- Contact all applicable vaccine manufactures for decision on vaccine viability. Provide them with all information on the excursion including temperatures, durations and vaccines involved.
- Contact the HDOH VFC Team and submit all documentation including:
 - *DDL data*
 - *Troubleshooting log*
 - *Manufacturer stability reports*
 - *5 days of stable temperature data following the date of the excursion(s)*

Submit documentation to HawaiiVFC@doh.hawaii.gov

Manufacturer Contact information

Dynavax: 1-844-375-4728

Merck: 1-800-672-6372

GlaxoSmithKline: 1-888-825-5249

Pfizer: 1-800-438-1985

or www.gskusmedicalaffairs.com

Sanofi Pasteur: 1-800-822-2463

Medimmune: 1-877-633-4411

Seqirus: 1-855-358-8966

Completing the Troubleshooting Log

1. Description of Event

- *What happened?*
- *Temperature & duration of excursion(s)*
- *Inventory of affected vaccine (lot #s, VFC vs. Private)*
- *Water bottles? Frozen coolant packs?*
- *Any prior issues with this unit?*



2. Action Taken

- *When did affected vaccines get placed in proper storage conditions?*
- *Who was notified? (Supervisors, VFC coordinators, etc.)*
- *What do you intend to do to prevent similar problems from occurring (if possible)*



3. Results

- *Manufacturer guidance?*
- *Viability determination*
- *Case numbers & representatives spoken with at each manufacturer*



Vaccine Storage Troubleshooting Record (check one) Refrigerator Freezer Ultra-Cold Freezer

Use this form to document any unacceptable vaccine storage event, such as exposure of refrigerated vaccines to temperatures that are outside the manufacturers' recommended storage ranges.

Date & Time of Event <small>If multiple, related events occurred, see Description of Event below.</small>	Storage Unit Temperature <small>at the time the problem was discovered</small>		Room Temperature <small>at the time the problem was discovered</small>	Person Completing Report	
Date:	Temp when discovered:		Temp when discovered:	Name:	
Time:	Minimum temp:	Maximum temp:	Comment (optional):	Title:	Date:
Description of Event <small>(If multiple, related events occurred, list each date, time, and length of time out of storage.)</small> <ul style="list-style-type: none"> • General description (i.e., what happened?) • Estimated length of time between event and last documented reading of storage temperature in acceptable range (2° to 8°C [36° to 46°F] for refrigerator; -50° to -15°C [-58° to 5°F] for freezer; -80° to -60°C [-112° to -76°F] for ultra-cold freezer (may be used for Pfizer COVID-19 vaccine). • Inventory of affected vaccines, including (1) lot #s and (2) whether purchased with public (for example, VFC) or private funds (Use separate sheet if needed, but maintain the inventory with this troubleshooting record.) • At the time of the event, what else was in the storage unit? For example, were there water bottles in the refrigerator and/or frozen coolant packs in the freezer? • Prior to this event, have there been any storage problems with this unit and/or with the affected vaccine? • Include any other information you feel might be relevant to understanding the event. 					
Action Taken <small>(Document thoroughly. This information is critical to determining whether the vaccine might still be viable!)</small> <ul style="list-style-type: none"> • When were the affected vaccines placed in proper storage conditions? (Note: Do not discard the vaccine. Store exposed vaccine in proper conditions and label it "do not use" until after you can discuss with your state/local health department and/or the manufacturer[s].) • Who was contacted regarding the incident? (For example, supervisor, state/local health department, manufacturer—list all.) • IMPORTANT: What did you do to prevent a similar problem from occurring in the future? 					
Results <ul style="list-style-type: none"> • What happened to the vaccine? Was it able to be used? If not, was it returned to the distributor? (Note: For public purchase vaccine, follow your state/local health department instructions for vaccine disposition.) 					

Final Reminders....

- If you're ever unsure about a temperature excursion, please reach out to the HDOH VFC Quality Assurance Team.
- The manufacturer stability calculators should only be used to determine vaccine viability if:
 - *1. Advised to do so by a member of the VFC Quality Assurance Team*
 - *2. The excursion is a single, one-time occurrence. Calculators should not be used for excursions with multiple occurrences or if there is a history of out-of-range temperature data.*
- We need to see 5 days of stable, within appropriate range, temperature data before we can clear a unit for use.
- Once you've submitted all your excursion documentation, please wait for guidance from the HDOH VFC Quality Assurance Team before resuming vaccination with affected vaccine.
- All temperature excursion documentation can be submitted to HawaiiVFC@doh.hawaii.gov. Please be sure to include: Facility Name, PIN# & Document Type in the Subject line.

Contact Info

For any VFC-related questions, please feel free to reach out to any member of our VFC QA Team

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HDOH VFC e-mail: HawaiiVFC@doh.hawaii.gov

Thank you for joining us!

Please complete the VFC Webinar Satisfaction Survey Here:

<https://forms.office.com/g/XStX9ewn6e>

