

## IHS Temporary Guidance on COVID-19 Vaccine Temperature Excursions

**Date Implemented: March 26, 2021**

The purpose of this guidance is to formalize the process for reporting temperature excursions previously established by the Indian Health Service (IHS) during webinars and via email communications.

Maintaining the vaccine cold chain is a critical element for ensuring vaccine viability and potency.

Anytime vaccine is stored outside the recommended manufacturer temperature ranges, even for short periods, it is considered a temperature excursion. There are important details to collect and document as soon as possible when an excursion is suspected or occurs in the effort to determine the viability of the vaccine.

With the complexity of the various COVID-19 vaccine products and variable storage stabilities, it will be important to track and monitor vaccine closely, paying special attention to short dating of products that are thawed or reconstituted, as appropriate. Redistribution efforts increase access to vaccine and allow for more equitable distribution; however, redistribution introduces considerable risk for temperature excursions.

### **Steps to take in reviewing and reporting a temperature excursion:**

1. Record the temperature excursion details. Immediately mark the vaccines as “Do Not Use” and sequester them in the most appropriate storage condition (fridge/freezer/Ultracold Freezer). Include details on or near the sequestered vaccine about the potential excursion, including the name and phone number of the individual working to determine the viability of the vaccine. Store vaccines that have had a potential temperature excursion per manufacturer's recommendations until steps 2-4 have been completed.
  - a. Collect and document the details of the potential temperature excursion, including the description of the event, the action taken, and the results using download all data logger information and collect temperature logs or vaccine transport logs.
  - b. Document the following details of the potential excursion using the **IHS COVID-19 Vaccine Temperature Excursion Worksheet**.
    - i. Affected vaccine and manufacturer, whether the vaccine was a prime or boost dose (if applicable), the number of doses, lot number, original expiration for that lot number, any different beyond use date and any additional information.
    - ii. The conditions under which the vaccines were stored at the time of the excursion.
    - iii. The conditions under which the vaccines are currently being stored.
    - iv. Whether the excursion was related to redistribution, an off-site/mobile clinic, or emergency transport.
    - v. Date and time the excursion started or was discovered, the date and time it ended (or was discovered), and the total duration of the excursion.
    - vi. Whether the temperatures were too warm with the maximum temperature, or too cold with the minimum temperature.
    - vii. Indicate any known potential cause and the details of the excursion, including collecting information from anyone that may have any knowledge of the circumstances (e.g., nursing, pharmacy, other staff).
    - viii. Note whether the affected vaccine was previously involved in a temperature excursion, and explain the resolution and any pertinent details of the previous excursion.
2. Alert the IHS COVID-19 Vaccine Task Force (VTF) of the potential excursion.

- a. Immediately email the Vaccine Task Force at [IHSCOVIDVaccine-Distribution@ihs.gov](mailto:IHSCOVIDVaccine-Distribution@ihs.gov) and the Area Vaccine Point of Contact (AVPOC). Provide a brief description of the event with I/T/U facility's name, point of contact, and phone number.
3. Contact the manufacturer and record the manufacturer's stability determination.
  - a. Contact the manufacturer and provide all details of the potential excursion.
  - b. Request and document the case/reference number and request any internal stability information from the manufacturer.
  - c. Document the manufacturer's determination of the vaccine viability on the worksheet.
4. Finish processing the vaccines based on the manufacturer's determination.
  - a. If manufacturer determines vaccines are viable and acceptable for use:
    - i. Remove "Do Not Use" sign, ensure vaccine is placed in appropriate storage and alert your team.
    - ii. Mark the boxes noting that there was an excursion for future reference.
    - iii. Vaccines are okay to administer. Rotate back into stock.
    - iv. Attempt to address the root cause of the excursion and ensure safeguards are in place for the future.
  - b. If manufacturer determines vaccines may not be viable and are NOT acceptable for use:
    - i. Follow guidance for return or disposal of non-viable vaccines. Discard vaccine vials according to local waste procedures and reverse distribution.
    - ii. Reach out to your Area Vaccine Point of Contact to determine next steps for getting additional vaccine.
    - iii. Document wastage in the VPoP providing a wastage reason selected from the pre-populated field and a free text description with additional detail.
  - c. If the manufacturer provides an unclear recommendation, contact the IHS Vaccine Task Force for review.
5. Submit documentation and attach relevant data reports.
  - a. Provide data logger reports and/or temperature logs or vaccine transport logs.
  - b. Email all documents and relevant details of the event and the disposition of the vaccine to the AVPOC and the IHS COVID-19 Vaccine Task Force at:  
[IHSCOVIDVaccine-Distribution@ihs.gov](mailto:IHSCOVIDVaccine-Distribution@ihs.gov).
6. Keep all records and documentation for six (6) years.

### **Termination Date**

This Guidance will expire, upon termination of the 2019 novel coronavirus (COVID-19) as a public health emergency for the entire United States pursuant to section 319 of the Public Health Service Act (42 U.S.C. § 247d).