# Vaccine Storage Recommendations

Helmer Scientific
June 2021

ARTICLE S3R054-D

## INTRODUCTION

Vaccine providers and program administrators face significant challenges as they navigate the selection and purchase of effective vaccine storage equipment. It is not always clear whether a refrigerator or freezer will meet a provider's needs. Providers should take great care when selecting vaccine storage equipment as proper storage is critical to ensure the safety and viability of life-saving vaccines.

A new vaccine storage standard, NSF/ANSI 456, that ensures storage units are tested against a protocol designed to reflect real-world use conditions will serve to demystify the selection process for end-users. This new vaccine standard was developed through collaboration with the Centers for Disease Control (CDC), National Sanitary Foundation (NSF), end users, equipment suppliers, vaccine manufacturers, and stakeholders in public health.

## THE CDC VACCINE STORAGE AND HANDLING TOOLKIT

Although the CDC Vaccine Storage and Handling Toolkit provides guidance that improves the safety and efficiency of vaccine storage, the CDC does not provide performance criteria for cold storage.

The CDC prohibits the use of dormitory style cold storage as these types of units are known to have temperature variances that can damage vaccines. The Vaccine Storage and Handling Toolkit recommends the use of "purpose-built" or "pharmaceutical-grade" vaccine refrigerators for this reason[1].

**Attributes of Temperature Performance for Vaccine Storage Refrigerators**

| | |
|---|---|
| Uniformity | The ability to maintain tight temperatures across all potential areas of a cabinet that may be used for storage |
| Stability | The ability to avoid wide swings of temperature related to compressor performance or other design elements |
| Recovery | The ability to recover to required temperatures for medication and vaccine storage after routine and extended door openings |

Helmer SCIENTIFIC

## CHALLENGES UNDERSTANDING PERFORMANCE OF VACCINE REFRIGERATORS

Performance differences between purpose-built vaccine refrigerators may be significant but may be identified only through testing that simulates real-world use related to load conditions and door openings, as well as measuring cabinet temperature across all potential storage locations.

**Vaccine load conditions:** Purpose-built vaccine refrigerators rely on airflow to maintain cabinet temperature and uniformity. Performance can vary greatly depending on how inventory is loaded and organized, and how much storage capacity is used by vaccine boxes.

In clinical environments, it is challenging to keep boxes and bins organized and vaccine refrigerators may be "stuffed" with boxes depending on available capacity. These real-world conditions impact how air is distributed in a cabinet and may result in poor uniformity and/or hot and cold spots in certain areas of the cabinet.

**Door openings:** To safeguard vaccines, the refrigerator cabinet must recover temperature quickly after door openings. In clinical environments, doors to vaccine refrigerators may be opened frequently which can stress refrigeration performance and overall temperature uniformity and recovery.

A study conducted by the NIST's Physical Measurement Laboratory (PML) indicated that in busy clinical environments a vaccine refrigerator may be accessed more than 30 times in a single hour.[2]

Vaccine refrigerators require specialized design in order to ensure appropriate performance with frequent door openings. The unit must be able to quickly recover temperature across every storage location inside the unit without causing the vaccines or medications to go below 2°C.

**Temperature uniformity:** In clinical environments, it is very common to use a single location within a cabinet to monitor temperature with a data logger or other temperature measuring device. Depending on the design of the vaccine refrigerator, there may be significant variation in temperature across different locations inside the cabinet.

Manufacturers use temperature mapping studies to evaluate uniformity across multiple locations within the refrigerator cabinet to identify any warm spots or cold spots (risks for freezing).

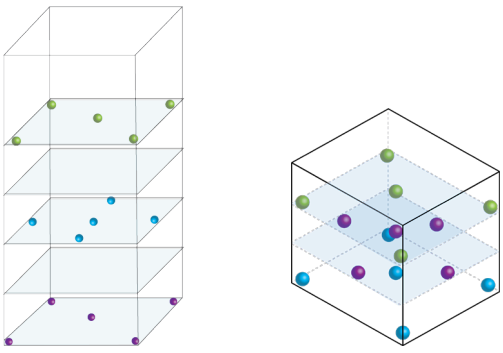

*Figure 1: Example probe locations in a vaccine storage cabinet used for temperature mapping studies to measure temperature performance.*

## NSF JOINT COMMITTEE FOR VACCINE STORAGE

Because vaccine storage performance requirements had not been clearly defined, the NSF Joint Committee on Vaccine Storage was formed in 2015 to develop a new standard. This committee comprises a diverse group of individuals representing the Centers for Disease Control (CDC), National Sanitary Foundation (NSF), end users, equipment suppliers, vaccine manufacturers, and stakeholders in public health.

The committee was responsible for creating a standard that ensures engineering controls are in place to assist in vaccines being stored safely under real-world conditions. Understanding that vaccine providers face a diverse range of conditions and levels of operator experience and expertise at clinics, private practices, and hospitals, the committee was focused on performance criteria aligned with how equipment is used in clinical environments

.

The NSF/ANSI 456 Vaccine Storage Standard was finalized in May 2021, and equipment manufacturers can now submit their products for independent testing and certification against the standard. Based on broad participation of this committee, it is expected this new standard will be widely adopted across the industry.

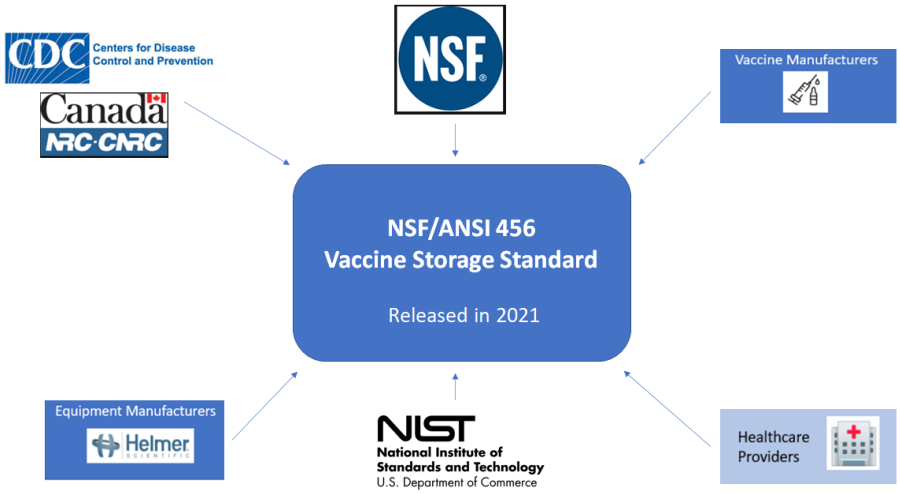


*Figure 2: New Vaccine Storage Equipment standard was developed by a diverse group of professionals committed to improving vaccine administration safety.*

## NSF TESTING PROTOCOLS

The NSF/ANSI 456 standard is designed to ensure vaccine storage equipment can maintain 5°C +/- 3°C across all potential storage locations under varying load conditions to simulate real-world clinical environments.

Protocols for standardized testing relate to empty and full inventory loads as well as door openings; these tests are designed to identify weak points in cold storage devices related to hot spots or cold spots in the cabinet, as well as testing recovery performance after door openings using small, weighted probes specially designed in conjunction with NIST to simulate actual vaccine temperature.

- **Probes:** Small aluminum weighted probes are used, instead of traditionally supplied glycol bottles, in this standard to better represent product temperature (aluminum weighted probes are smaller and more responsive than typical glycol bottles).
- **Steady-state evaluations:** Occur with the exterior door of the refrigerator remaining closed for the entire evaluation period.
- **Door opening evaluations:** Use a procedure to simulate routine, short door opening periods (dispense or replace product) and a long door open period to simulate inventory loads and counts.

The standard recognizes that door openings may result in temperatures temporarily exceeding this range, but equipment must have the capacity to quickly recover into recommended ranges. This testing protocol will help ensure equipment designed to comply with the standard will provide safe and effective storage for refrigerated medications and vaccines.

Helmer Scientific products have been tested and meet the performance requirement in the new standard.

**Helmer GX Solutions Upright Refrigerator - Fully loaded with extended door opening**

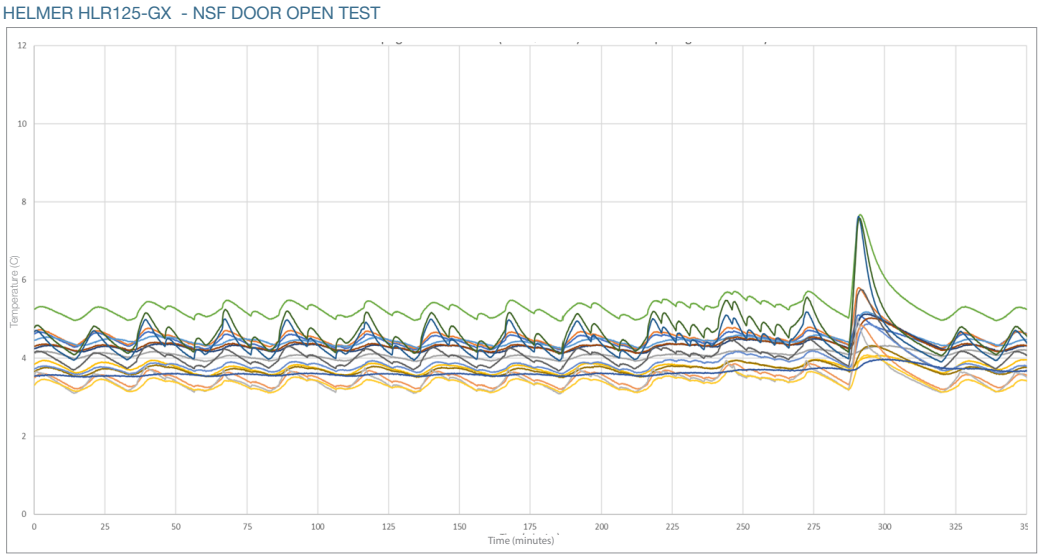


*Figure 3: Helmer Scientific GX Solutions HLR125-GX was tested according to the NSF Vaccine Storage Equipment standard that includes an extended door opening to simulate real-world use. The Helmer Scientific GX Solutions refrigerator recovered quickly after the extended door opening.*

**Helmer GX Solutions Upright Freezer - Fully loaded with extended door opening**

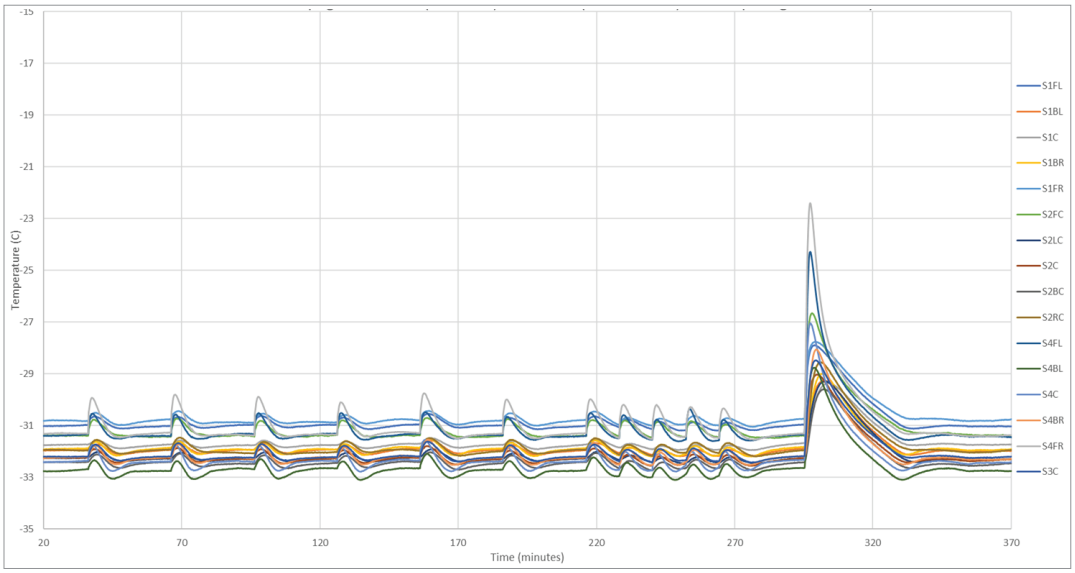


*Figure 4: Helmer Scientific GX Solutions HLF125-GX was tested according to the NSF Vaccine Storage Equipment standard that includes an extended door opening to simulate real-world use. The Helmer Scientific GX Solutions freezer recovered quickly after the extended door opening.*

## THE FUTURE OF VACCINE STORAGE TESTING

The CDC and clinicians have made significant progress to help ensure the safe storage of vaccines through the CDC Vaccine Storage and Handling Toolkit. Ongoing efforts to further protect public health via safe and effective vaccine storage and handling continues through the development of this new vaccine storage performance standard.

To comply with the new standard, Helmer Scientific refrigerators and freezers, as well as equipment from other suppliers, will be tested to the standard by a third-party independent testing company to indicate appropriate performance and compliance for vaccine storage.

Helmer Scientific has accounted for this standard in the development of all GX Solutions refrigerators and freezers. Helmer Scientific designs GX Solutions refrigerators and freezers to ensure appropriate performance, and ultimately support effective immunizations.

## ACKNOWLEDGMENTS


1. https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html
2. https://www.nist.gov/news-events/news/2016/02/vaccine-fridge-field-study-opens-doors-new-standards




Helmer SCIENTIFIC