Vaccine storage standards by NSF International

In a time where there is global urgency around quickly producing and deploying as many COVID-19 vaccines as possible to prevent the continued adverse affects of the SARS-CoV-2 crisis, the World Health Organization estimates that as much as 50% of vaccines are wasted yearly [1]. A leading cause of that wastage is exposure of vaccines to freezing or inappropriate temperatures during storage prior to inoculation.

Keeping the cold chain, which is the temperature-controlled supply chain that runs from the time a vaccine is produced until it's administered, within the validated temperature range for a specific vaccine ensures its effectiveness. When exposed to temperatures outside of these ranges, vaccines can quickly become ineffective. The entire batch must then be discarded, resulting in loss of time, resources, and potentially public confidence. If this deviation isn't detected, you run the risk of delivering ineffective vaccines to patients.

In the United States, there was no official standard for vaccine storage equipment in clinics, pharmacies, and other vaccination sites. The U.S. Centers for Disease Control and Prevention (CDC) does provide an annually updated guide called the Vaccine Storage and Handling Toolkit that lists guidelines for how to measure the cabinet temperature and gives some best practices on the handling of vaccines. However, it stops short of detailing the temperature performance, design, and documentation requirements for a vaccine refrigerator and freezer to prevent product loss [2].

A new standard has been published by NSF International (formerly the National Sanitation Foundation) [3]. The NSF put together a multi-institution committee whose goal was to define a set of performance standards for vaccine refrigerators and freezers to help providers select the best products to minimize vaccine wastage. The committee includes representatives from the CDC, state health department immunization programs, nonprofit organizations, and vaccine storage equipment manufacturers, including Thermo Fisher Scientific.

Based on the analysis of data from real-life usage within clinics, pharmacies, and vaccination sites, the committee created a new standard, NSF 456–Vaccine Storage. Its purpose is to help vaccine administrators choose storage units that have been certified to stay within proper temperature ranges to ensure the safety and efficacy of vaccines, and ultimately the public.

Providers and manufacturers, like Thermo Fisher, have historically understood the need for high-quality products to protect vaccines. This has led to the development of a unique class of specialized, high-performance refrigerators and freezers with more precise and sophisticated temperature control features than their typical household or commercial-grade counterparts.

These specialized vaccine storage refrigerators and freezers generally meet applicable safety requirements like UL 61010-2-011 or UL 471, the Standard for Refrigerated Laboratory Equipment, and are assessed against them. These standards are used to evaluate and mitigate the risk of electrical shock, casualty, and fire hazards. They are all important points to consider and help ensure a higher level of safety; however, they don't speak to performance, functionality, and design intent. Performance is the most important aspect of continuous vaccine protection and a key aspect of this standard.

The NSF 456 standard is broken down into two temperature ranges: refrigerated (2 to 8C) and freezer (-15 to -50C.) But both look at the same aspects of performance.

Units are tested under a very specific test procedure and conditions and at accredited third-party testing organizations to ensure consistency in data collection and results.

The temperature probes used in the test are called vaccine simulation devices (or VSDs) and are designed to mimic the size and mass of a vaccine vial. The VSDs are placed in three separate horizontal planes (Fig. 1.)

One plane is located at the top of the usable space or on a shelf or drawer that is placed in its uppermost position, one located at the bottom of the usable space (including the floor if it is accessible), and one bisecting the vertical distance between the top and bottom planes. Five VSDs are placed on each plane.

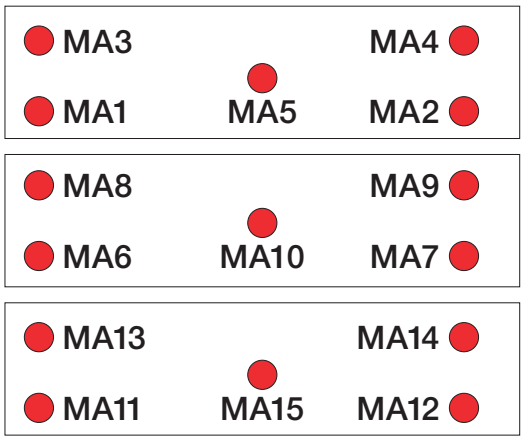

Figure 1. Diagram showing temperature probe placements throughout the cabinets in a NSF 456 test unit.

The performance requirements are broken down into three tests.

The first is a closed-door test. During this test all points must stay within the allowed range. There is accommodation for auto-defrost functionality in this test which allows 15-minutes to recover back to the upper bound of the acceptable temperature range.

The second test is a short door opening test- this is 3 hours of openings occurring every 10 minutes. This is followed by 1 hour of openings every 5 minutes. During this test the VSDs must to stay within the bounds.

The last part of the test is a long door opening. This test happens shortly after the short door openings and last 3 minutes. Once the door is closed, all points in the cabinet must recover back below 8c for refrigerators or -15C for freezers within 15 minutes.

The results for this test method can be found in Fig. 2 for a loaded and an empty TSX Series High Performance Pharmacy refrigerator.

The two door opening tests were designed to mimic typical use within a clinic. It was found that during routine use door openings are approximately 8 seconds long, but they happen at a high frequency.

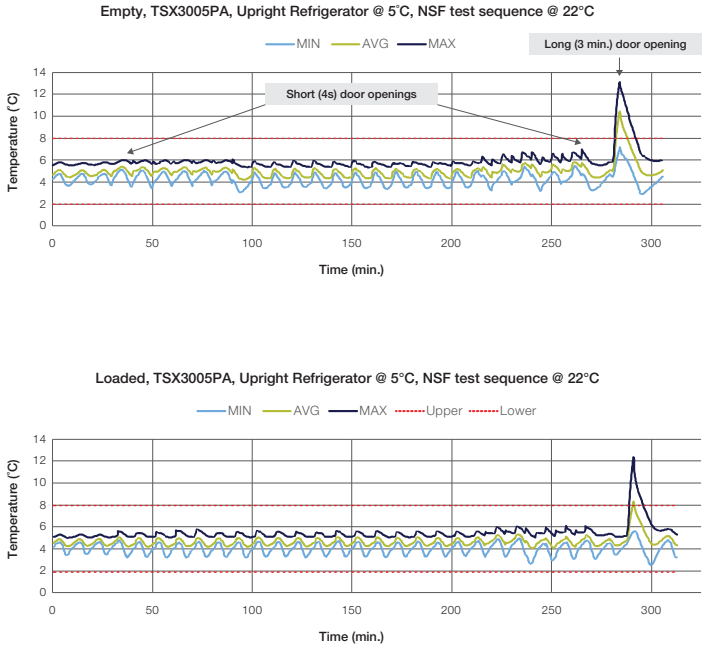

Figure 2. Graphs showing performance of a TSX 30 cubic foot pharmacy refrigerator during the NSF 456 test.

This is a typical dosage retrieval. The longer test mimics the bulk loading or unloading of product, which happens much less frequently but the duration is much longer.

At Thermo Fisher, we've kept the protection of vaccines in mind while we innovate. That is why Thermo Scientific™ TSX Series High-Performance Refrigerators and Freezers are purpose-built to store critical products, like vaccines, that are sensitive to temperature variation. A selection of the TSX Series are now certified to this standard.

We looked closely at temperature performance in all parts of the usable spaces in the cabinets. While some manufacturers publish performance data, the methodology used to generate the data are often inconsistent, which could lead to an improper understanding of a product's capabilities. That is why it is crucial to understand the meaning and test methodology behind thermal performance data, including that of the TSX Series refrigerators and freezers.

The NSF 456 standard creates a clear comparison for those looking for vaccine cold storage. To help with this comparison Thermo Fisher publishes NSF technical data sheets for those products certified to the standard. These are information sheets that summarize the results of the test.

Many traditional vaccine storage units may not meet the new standards developed by the NSF. Thermo Scientific TSX Series High-Performance Pharmacy refrigerators and auto defrost freezers are certified to meet the NSF-456 standard's performance, design, and compliance requirements for proper vaccine storage.

At Thermo Fisher, we strive to provide our customers and partners with the products, services, and information they need to make the world healthier, cleaner, and safer.

References

1. Monitoring vaccine wastage at country level (2005), World Health Organization, WHO/V&B/03.18. Rev.1, **http://apps.who.int/iris/bitstream/handle/10665/68463/WHO_VB_03.18.Rev.1_eng.pdf?sequence=1&isAllowed=y.**
2. 2. The U.S. Centers for Disease Control and Prevention Vaccine Storage and Handling Toolkit.
3. 3. NSF 456–Vaccine Storage (2021), **https://standards.nsf.org/kwspub/public/stds**.