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.

A simple but important metric used to assess refrigeration performance is temperature uniformity, which is tested by measuring the maximum temperature difference between all points in a unit at any specific moment in time. In this example, we have a 20 cubic foot conventional laboratory/clinical grade refrigerator and a purpose-built high-performance vaccine refrigerator. Figure 1 shows the placements of open-air thermocouples within each cabinet. Table 1 and Table 2 show the corresponding data from a conventional refrigerator and a purpose-built Thermo Scientific™ TSX Series High-Performance Pharmacy Refrigerator, respectively.

As highlighted in Table 1, the temperature drops below 2°C at every single point in the cabinets of the conventional refrigerator unit. Meanwhile, the temperature stays within the 2–8°C range in the TSX Series refrigerator. In other words, vaccines stored in the conventional unit would be routinely exposed to freezing temperatures that would affect efficacy in every part of the cabinet. If you go by current CDC guidelines and use a single digital data logger with a weighted probe, depending on where you place the probe and how often readings are taken, you may not be aware that your vaccines are at risk.

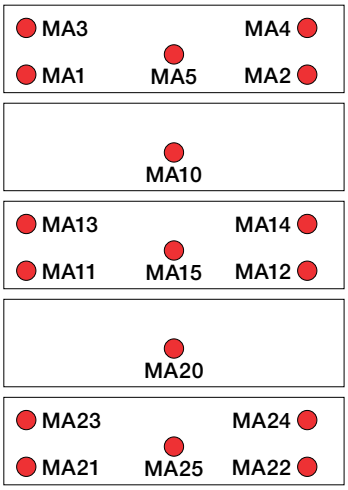

Figure 1. Diagram showing temperature probe placements throughout the cabinets in a conventional refrigerator.

Table 1. Temperature map data (°C) from a conventional laboratory refrigerator.

	MA1	MA2	MA3	MA4	MA5	MA10	MA11	MA12	MA13	MA14	MA15
Average	4.3	4.3	4.3	4.3	4.2	4.0	3.9	3.9	3.8	3.9	3.8
Maximum	7.8	7.8	7.8	7.7	7.7	7.1	6.6	6.6	6.6	6.6	6.6
Minimum	–2.7	–2.2	–2.6	–2.3	–3.3	–1.8	–0.7	–0.8	–0.6	–0.6	–1.2

	MA20	MA21	MA22	MA23	MA24	MA25
Average	3.7	3.9	3.9	3.8	3.9	3.8
Maximum	6.4	6.4	6.4	6.3	6.4	6.4
Minimum	–0.2	0.5	0.8	0.3	0.8	0.5

Table 2. Temperature map data (°C) from a TSX Series High-Performance Pharmacy Refrigerator.

	MA1	MA2	MA3	MA4	MA5	MA10	MA11	MA12	MA13	MA14	MA15
Average	5.3	5.2	5.1	5.1	5.1	5.0	5.2	5.1	4.9	4.6	5.1
Maximum	6.6	6.4	6.3	6.4	6.4	6.4	6.6	6.4	6.4	6.0	6.6
Minimum	3.8	4.0	3.9	3.9	3.7	3.7	3.8	3.7	3.0	3.1	3.4

	MA20	MA21	MA22	MA23	MA24	MA25
Average	5.0	5.6	5.1	5.3	5.1	5.1
Maximum	6.4	6.8	6.5	6.3	6.4	6.5
Minimum	3.4	4.3	3.6	4.4	3.8	3.6

Temperature uniformity can give a clear baseline understanding of how a refrigerator unit might perform, but it does not show how it will react to any environmental change or user interaction. The new standard from the NSF dictates the use of weighted probes to more accurately represent vaccine vials to gather performance data using a test method built to mirror typical usage. This test includes both long and short door-opening sessions as well as closed-door sessions. These tests include both empty and loaded cabinets and provide information about where the probes should be placed. This additional data helps show how typical use of vaccines in a clinic, hospital, or pharmacy will impact the performance of the storage unit, and inevitably the performance of the vaccines within.

Even within the vaccine class of refrigerators and freezers available today from multiple manufacturers, the performance, functionality, and design intent vary greatly. These new standards will help clearly define which products on the market are truly suitable for vaccine storage.

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. This series is intended to meet the forthcoming standards.

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.

To demonstrate the capabilities of our products, Thermo Fisher publishes technical data sheets (TDSs) for our cold-storage equipment. These are information sheets that summarize important data for our products. The thermal performance data section summarizes the typical performance of a specific model. The values listed are intended to be used to help assess whether the product is likely to meet the storage needs of a use case. The values are generated in a controlled environment, and the data are collected according to very specific test procedures.

Summarized on the TDS is the performance of the specific test unit used for the test (MSO Number). Important definitions in this section are:

- **Average cabinet temperature:** The average temperature of all the unweighted type T thermocouples (TCs) placed throughout the usable volume of the cabinet over the entire test period at the specified setpoint temperature.
- **Peak variation from setpoint:** The highest TC temperature difference over all locations and times of the entire cycle test period. It is simply the difference between the highest and lowest temperatures observed during closed-door testing of the sample unit.
- **Uniformity:** The maximum temperature difference between all TCs at any specific moment in time. We publish the average uniformity during the cycle portion of the test.
- **Stability:** The maximum temperature difference over the entire test for any specific location. The average stability during the cycle is the value published.
- **1-minute door open recovery:** The time between the start of a 1-minute door opening and when the average of all the TCs is again below the setpoint.

Many products available today for vaccine storage may not meet the new standards developed by the NSF. For this reason, it is important to have discussions with your cold-storage providers now to understand their plans in supporting your ongoing need to properly protect the vaccines you store. 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.

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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. The U.S. Centers for Disease Control and Prevention Vaccine Storage and Handling Toolkit.
3. NSF 456–Vaccine Storage (2021), **https://standards.nsf.org/kwspub/public/stds**.

Ordering information

Product	Temp. set point range (set point)	Capacity cu. ft. (L)	Electrical (plug)	Doors	Shelves	Defrost	Certification	Interior dimensions (D x W x H)	Exterior dimensions (D x W x H)	Shipping weight	Cat. No.
Refrigerators											
TSX Series High-Performance Undercounter Lab Refrigerators	3–7°C (5°C)	5.5 (156)	115 V, 60 Hz (NEMA 5–15)	1 glass	3	Auto	UL, cUL	20.5 x 19.5 x 23 in. (52 x 49.5 x 58.4 cm)	26 x 23.6 x 31.8 in. (66 x 59.9 x 80.7 cm)	147 lb (66.7 kg)	TSX505GA
TSX Series High-Performance Pharmacy Refrigerators		23 (650)			6 wire baskets			28.5 x 24 x 58.0 in. (72.3 x 61.0 x 147.3 cm)	37.8 x 28.0 x 78.5 in. (71.1 x 96.2 x 199.4 cm)	531 lb (241 kg)	TSX2305PA
		29.2 (826)						28.5 x 30.0 x 58.0 in. (72.3 x 76.2 x 147.3 cm)	37.3 x 34.0 x 78.5 in. (94.7 x 86.4 x 199.4 cm)	541 lb (245 kg)	TSX3005PA
Freezers											
TSX Series High-Performance –30°C Auto Defrost Freezers	–35° to –15°C (–30°C)	11.5 (326)	115 V, 60 Hz (NEMA 5–15)	1 solid	4	Auto	UL, cUL	21.8 x 20.0 x 52.4 in. (55.4 x 50.8 x 133.1 cm)	31.1 x 24.0 x 73.0 in. (79.0 x 61.9 x 185.4 cm)	335 lb (152 kg)	TSX1230FA
		23.3 (659)						28.5 x 24 x 58.0 in. (72.3 x 61.0 x 147.3 cm)	37.9 x 28.0 x 78.5 in. (96.2 x 71.1 x 199.4 cm)	423 lb (192 kg)	TSX2330FA
		29.2 (826)						28.5 x 30.0 x 58.0 in. (72.3 x 76.2 x 147.3 cm)	37.9 x 34.0 x 78.5 in. (96.2 x 86.4 x 199.4 cm)	439 lb (199 kg)	TSX3030FA

* Contact your Thermo Fisher representative to confirm status of NSF certification.

Find out more at **thermofisher.com/vaccinestorage**

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