



NEWSLETTER



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## Thermal Mapping Validates Controlled Temperature Chamber Compliance

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Outdoor thermal measurements and fluctuation have received a lot of attention in Ohio this winter, especially when temperatures dipped well below freezing.

There's an *indoor* type of thermal measurement and monitoring that's also important to contractors, developers, and managers of facilities where temperature-sensitive pharmaceuticals, food, chemicals, and other products are manufactured, warehoused, and distributed throughout the logistics supply chain.

### What is temperature mapping?

Temperature mapping, also known as thermal mapping, is the practice of collecting and analyzing data over a specified period of time to validate that Controlled Temperature Chambers and systems perform as designed to keep frozen, refrigerated, and ambient-temperature products within their specified temperature and humidity ranges for product safety, efficacy and quality.





## Who should be concerned about temperature mapping?

Everyone who consumes frozen or refrigerated foods, anyone who uses pharmaceutical or over-the-counter medications, and those who value quality products that perform as promised, benefits from temperature mapping protocols and compliance.



In construction and facilities management, general contractors and construction managers use the temperature mapping process to validate that the building (or chambers within the building) meets design and operating specifications, so the building can be turned over to the owner. Then it's the building owner's responsibility to maintain the facility according to the temperature standards.

## Validation is an integral part of the project cycle.

Validation is vitally important, but is just one aspect of the complex compliance and quality assurance project cycle, which includes activities such as design, documentation, training, calibration, and maintenance.

- **During the design phase**, building and equipment engineers specify the operating conditions and performance requirements for the entire building and any defined chambers (e.g., freezer or refrigerated rooms within the building).





- The specified **Temperature-Controlled Equipment Qualification** is the process used to ensure and prove that the installed temperature-controlled equipment can maintain the specified critical parameters throughout the entire chamber under normal operating conditions. The testing is customized for each building, but typical tests include:
  - A 7-day **empty-building study** with the HVAC operational.
  - An **open door study** to see how temperatures and humidity fluctuate and recover when doors to the freezer, cooler, ambient air spaces and dock doors are opened.
  - A **power failure study** that measures how long it takes the building spaces to fall out of compliance and how long it takes the building to recover.
  - **After a building is filled**, operators are required to perform temperature mapping twice a year, once each during summer and winter.
- **Temperature mapping fits into the Operation Qualification (OQ) and Performance Qualification (PQ) steps** of the qualification process. Specifically, mapping an empty space just after installation could be part of an OQ plan, while mapping when the space is loaded, simulating operating conditions, can be part of PQ.

## How temperature mapping is performed.

To prepare for testing, a validation consultant leading a team of specialists provides specified guidelines and best practices for qualification and temperature mapping.

- Based on those specifications, GCI's team establishes the protocol for setting up the testing.
- Once the validation consultant and owner approve the plan, then GCI's technicians place the specialist's calibrated temperature sensors or data loggers in specific, predefined locations inside the Controlled Temperature Chamber being tested.
- Sensors must be undisturbed for the specified period of time.
- When the testing is complete, the data loggers are collected, data is downloaded, and the validation consultant creates the final report to the end user.

The results will show precisely what is happening inside the space such as severe temperature fluctuations and hot or cold spots. The data will be used to determine if the storage units meet the specification or requirements that have been set for the intended products that will be processed or stored in the facility.



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