

NIST Certification: How Therma Promotes FDA Compliance

Learn more about how Therma can help your business avoid fines, shutdowns, and recalls.

In 2010, the CDC released a report on foodborne illness, concluding that 1 in 6 Americans get sick every year from unknowingly consuming microbes and chemicals. Further, the cause of high rates of food-borne illness was a lack of oversight in food production, manufacturing, and transport. These findings spurred the government to pass the Food Safety and Manufacturing Act (FSMA) in 2011. This law required the use of certified electronic temperature monitoring in food manufacturing. In order to receive certification, temperature monitoring systems must be evaluated for quality. Therma simplifies this process and makes it easy to comply with federal regulations.

Read on to find out more about food manufacturing regulatory standards and how Therma can help your facility comply with the FSMA.

Revised FDA Food Safety Standards

To accomplish the goal of the FSMA, the Food and Drug Administration (FDA) created new standards and practices to prevent contaminated food from being distributed. Some of the new regulations included:

- **Product Safety Assurance:** The FDA mandates that food producers take a science-based approach to quality, including analyzing storage conditions for potential contamination sources.
- **Increased Inspection Frequency:** This rule requires the FDA to inspect facilities at least every three years.
- **Preventive Controls:** Every food processing facility is responsible for creating a plan to mitigate contamination. Controls include monitoring facility temperature and humidity conditions and keeping certifiable records to prove that temperature abuse didn't occur.

Violating these standards comes with penalties that range in severity. Some of the lesser consequences include warning letters and court injunctions. Continued violations or refusal to comply with the requested actions will lead to shutdowns, fines, seizures, and even prison time.

Temperature Monitoring and FDA Compliance

The FDA requires the use of electronic temperature monitoring devices as part of its regulations. Additionally, the FDA mandates operators produce six months of temperature logs during an inspection. They require this to prove that temperature abuse has not occurred in the handling of products. Records are essential because temperature abuse is one of the five

primary factors in contamination outbreaks.

Current ordinances require twice-daily inspections of cold storage areas. New technology has offered an automated approach to temperature monitoring. Remote monitoring systems record conditions, such as storage temperature digitally, using sensors. From there, sensors transmit data to a centralized location for record-keeping.

Remote Temperature Monitoring Options

Manufacturers can choose between a variety of temperature monitoring options to stay compliant with FDA regulations. They are grouped roughly into the following categories:

- **Wired Solutions:** Wired sensors are embedded into environments and use physical connections to transmit information via Ethernet.
- **Bluetooth and WiFi:** These sensors are wireless and rely on Bluetooth to transmit data to a centralized hub and WiFi to send data to mobile devices and computers. The downside of these devices is the unreliability of these signals in steel environments.
- **LoRaWAN Sensors:** These wireless sensors use Long Range Radio to transmit data instead of Bluetooth and WiFi. LoRaWAN sensors, such as Therma, communicate data effectively in environments that Bluetooth and WiFi cannot.

When evaluating which variety of sensors to implement in a food manufacturing facility, it's essential to keep in mind the data's reliability. The FDA needs verifiable, scientific proof of the efficacy of temperature monitoring systems used in food manufacturing. While LoRaWAN sensors are more reliable, they also need to be certified as effective. For more information about the difference between LoRaWAN and other temperature monitoring options, check out this [article](#).

NIST Certification

In the latest food code, the FDA stipulates that Food temperature measuring devices shall be calibrated per the manufacturer's specifications as necessary to ensure their accuracy. The FDA works in tandem with the National Institute of Standards and Technology (NIST) to establish criteria for food manufacturers to follow.

NIST is a government agency that regulates measurement and technology standards, determining the efficacy of Sensors by subjecting them to a variety of tests to measure their effectiveness. To receive certification, sensors must be proven effective within a +/- 1.8 degrees Fahrenheit margin of error.

Therma's NIST Certified Temperature Sensors

To serve the food manufacturing industry, Therma provides NIST certification of our sensors

upon request. We utilize an independent, 3rd party vendor verified by the Department of Commerce. Additionally, Therma's data is backed up digitally with our easy-to-use dashboard app. When inspectors ask to see your records, Therma's app allows you to provide them Instantly.

Interested in Working With Therma?

For more information on how Therma can help your manufacturing facility run smoother, chat with our customer service team, purchase sensors online, or request a demo with a Therma representative.