

for

NABH & JCI

Auditing

Temperature Calibration &
Temperature Monitoring Matters
WHO!!!



Standards used in Calibrations

Basic principle of calibration

Temperature Data Loggers

- IOT / USB Port



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Manufactures of Ice Line Refrigerator (ILR), Ice Lined Deepfreezer (ILDF), Ice Lined Blood Bank Refrigerator (ILBBR)
CE, ISO 9001-2015, ISO 13485-2016, WHO - GMP Certified and WHO PQS E03 compliant
GEM Seller ID: 3E03180000324808

COLDCHAIN CONTROLS-TEMPERATURE CALIBRATION SERVICES:

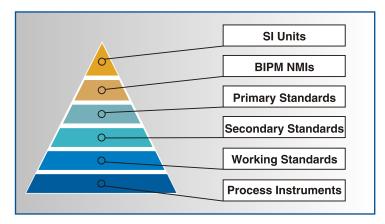
Common things calibrated with a temperature calibrator includes thermometers, thermocouples, thermistors and temperature transmitters.

The performance of these temperature instruments is often critical to optimized operation of the process manufacturing plant or proper functioning of the plant's safety systems. Process temperature instruments are often installed in harsh operating environments, causing their performance and the performance of their sensors to shift or change over time. Keeping these devices measuring temperature within expected limits requires periodic verification, maintenance and adjustments.

Temperature Calibration is the process of configuring an instrument to provide a result for a sample within an acceptable range. The instrument can then provide more accurate results when samples of unknown values are tested in the normal usage of the product.

We (calibration professional) perform temperature calibration by using a calibrated reference standard of known uncertainty (by virtue of the calibration traceability pyramid) to compare with a device under test records the readings from the device under test and compares them to the readings from the reference source.

STANDARDS USED IN CALIBRATIONS:



ISO/IEC 17025 is the quality standard that calibration laboratories use to ensure they produce valid results.

BASIC PRINCIPLE OF CALIBRATION:



Temperature Calibration is the activity of checking, by comparison with a standard, the accuracy of a measuring instrument of any type. It may also include adjustment of the instrument to bring it into alignment with the standard.

Temperature Calibration of measuring instruments has two objectives: it checks the accuracy of the instrument and it determines the traceability of the measurement. In practice, we undertake repairing / replacing the device if it is out of calibration.

NIST STANDARD FOR CALIBRATION:

NIST traceable calibration is an assurance program that certifies that a laboratory or manufacturer is fully equipped to calibrate equipment to the National Institute of Standards and Technology (NIST) standards and that any products offered by that manufacturer will match those NIST-maintained measurement standards.



Consequence of equipment is not being calibrated regularly. Equipment will not give accurate measurements. When the measurements are not accurate, the final results will also be inaccurate, and the quality of the product will be sub-standard.

RISKS OF NOT CALIBRATING REGULARLY

- > Product Quality. ...
- Uncalibrated Instruments Can Damage the products kept inside due to wrong display of temperature measurements...
- ➤ Increase In The Overall Cost and Maintenance. ...
- ➤ Accredition (NABH/JCI) Non Compliance (NC)

TEMPERATURE CALIBRATION



CALIBRATION ACCREDITATION:

When calibrations are performed, it's important to be able to trust the process by which they are performed. Calibration accreditation provides that trust. Accreditation gives an instrument owner confidence that the calibration has been done correctly.

Temperature Calibration accreditation is a process has been reviewed and found to be compliant with internationally accepted technical and quality metrology requirements. ISO/IEC 17025 is the international metrology quality standard to which calibration laboratories are accredited.

Accreditation services are provided by independent organizations that have been certified to do this type of work in India we follow NABL(National Accreditation Board of Laboratory) to all the NABH/JCI certified Hospitals The purpose of calibration is to help assure precise measurements. The benefits of calibration include improving safety as well as false acceptance and rejection of products, increasing efficiency, and extending the life of equipment. In terms of ROI, calibration is often among the best investments a hospital can make.

Hospitals / Institutions performing measurement where the results will make a critical decision such as a safety test must have their equipment calibrated so that the performance is known and fit for purpose. This is especially important the results to correlate with others around the world.

"All mechanical parts wear, and all electronic components drift over time, so a measuring instrument will not measure accurately to its specifications forever, it must be calibrated routinely to make sure that it operates properly and makes measurements as per its product specifications, and those results can be duplicated by others around the world because the calibration system is traceable to a common global reference. "In short, if measurement results matter, calibration matters."

Coldchain Controls temperature calibration services to ensure safe/proper working of that a device will remain calibrated correctly in the operating conditions specified as per the manufacturer's manual for a particular period such as six to 12 months.

Instruments that get calibrated on the right schedule and by a competent professional could help a company prosper. Conversely, instruments that are calibrated incorrectly or infrequently could cause confusion, offer misleading results and even compromise customer safety.

Temperature Monitoring Data Loggers

Vaccines are biological products that can lose their potency if exposed to excessive heat and/or freezing. Different vaccines have different sensitivity to freezing and heat; it is because of this phenomenon that monitoring the temperature of vaccines during storage and transportation is vital. Temperature monitoring devices are needed to keep track of the temperature to which the vaccines and diluents are exposed. Based on the data from these devices; important decisions may be made. This includes using the vaccine if the temperature is within the recommended excursion range, conducting a shake test if freezing is suspected or discarding the vaccine

Hospitals/Clinics

In hospitals and clinics, defined environmental values have to be maintained: Whether this relates to the storage of Vaccines/Drugs and blood reserves, clean rooms and wards. Measuring solutions offer you reliable protection from product losses and compliance violations for the Accreditation Audit(NABH/JCI/Drug Inspectors)

- Systematic IAQ monitoring
- ➤ Ensure correct storage of vaccines, samples and blood reserves
- ➤ Warning in the event of limit value violations
- > Special kits for Ice Lined medical refrigerators

Distributors/Pharmacies

To store sensitive medicines, temperatures need to be kept constant. Pharmacies are obligated to monitor and document these values. Temperature measuring solutions from Data Logger support pharmacies in their important work and prevent batches from having to be discarded:

- > Continuous monitoring of temperature
- Automatic documentation
- > Alarm function when limit values are exceeded
- > Special kits for medical refrigerators

