

	Standard Operating Procedure Calibration Verification of Digital Temperature Devices		SOP Number G-202	Revision 5
			Effective Date 12/14/23	Page Page 1 of 5
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1.0 Purpose

The purpose of this procedure is to describe the process for the single point calibration verification of digital temperature indicating devices.

2.0 Scope

This procedure is intended for the calibration verification of digital temperature reading devices that are a self-contained unit (i.e. kangaroo thermometers, thermocouples, probe thermometers, and other free standing NIST traceable temperature reading devices). This SOP also applies to equipment with a fixed temperature indicator (i.e. water baths, incubators, ovens, gummy manufacturing equipment etc.).

This procedure is not applicable to digital temperature/humidity sensors used in DicksonOne Data Loggers.

3.0 Responsibility

- 3.1 It is the responsibility of all personnel to follow this procedure.
- 3.2 It is the responsibility of QC Laboratory Management to ensure the procedure is current and is being followed.
- 3.3 It is the responsibility of the Metrologist to ensure the digital temperature indicators being used are within their calibration date as per SOP G-201 Calibration Program.
- 3.4 It is the responsibility of the Metrologist to keep current calibration certificates for all devices in this procedure as per SOP G-201 Calibration Program.

4.0 Definitions

- 4.1 **ISO** – International Organization for Standardization
- 4.2 **IEC** – International Electrotechnical Commission
- 4.3 **NIST** – National Institute of Standards and Technology
- 4.4 **ANSI** – American National Standards Institute
- 4.5 **NCSL** – National Conference of Standards Laboratories
- 4.6 **Fixed Temperature Device** – A temperature probe or sensor that is a built into production or analytical equipment and gives a reading on the equipment's interface
- 4.7 **Digital Temperature Device** – A temperature measuring device that is not integrated into any other equipment and gives readings from the device's display
- 4.8 **QC** – Quality Control

5.0 References

- 5.1 G-201, SOP, Calibration Program
- 5.2 G-201-F2, Form, Calibration Certificate
- 5.3 B-911, SOP, Continuous Gummy Manufacturing Process
- 5.4 B-911-F1, Form, Gummy Inline Equipment Verification Log

6.0 Procedures

- 6.1 It is recommended that digital temperature devices (devices that are **not fixed**) are replaced at least every five years. Digital Temperature Devices that can be calibrated must be calibrated by an ISO Certified external calibration lab at least once every five years and must have an accompanying certificate.

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6.2 For equipment with fixed digital temperature devices and specific calibration instructions, the device may be adjusted by personnel familiar with and qualified to perform the adjustment.

6.2.1 The common specification for verification is +/- 2°C of reference temperature unless otherwise specified by the needs of the application or recommended by the equipment manufacturer. The common verification cycle for temperature indicators is 1 year.

6.2.1.1 For instruments such as ovens and incubators that have a digital readout of the temperature, the fixed temperature of the device can be manually adjusted to the fixed point temperature using a NIST traceable reference. If the digital display is out of specified limits an offset can be recorded on the calibration verification documentation and the indicator labeled with the offset adjustment.

6.2.1.2 All instrument information, calibration verification and environmental data should be documented on form G-201-F2 Calibration Certificate.

6.3 For gummy line production, temperature indicators are integrated into the manufacturing equipment and display on the manufacturing equipment's user interface. Verify that the temperature probes are operational as per SOP B-911 and document on Form B-911-F1. If temperature readings are unable to be verified, refer to the supervisor and the troubleshooting section of the equipment's instruction manual.

6.4 Quarterly Device Verification

6.4.1 For QC Laboratory temperature devices only, on a quarterly basis, each temperature device should be challenged using a NIST traceable thermometer. The purpose of this challenge is to ensure the temperature device is functioning as needed.

6.4.1.1 Only devices used for temperature verification need to be challenged.

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6.4.1.2 Allowed ranges for challenge is $\pm 2^{\circ}\text{C}$.

6.4.1.3 Results should be captured in a laboratory notebook.

6.4.1.4 If temperature device does not meet the acceptable criteria then it should be removed from use.

6.5 Verification Process For devices :

6.5.1 For use as a reference standard, select a NIST traceable temperature gauge that has been externally calibrated and verified in compliance with ISO/IEC and/or ANSI/NCSL requirements. Internally calibrated temperature gauges do not qualify as reference standards.

6.5.2 Select a temperature as the reference point that pertains to the instrument being verified. For example: if the temperature indicator is used at ambient temperatures, verify at room temperature. If the temperature indicator is used to monitor a refrigerator verify at a temperature within the acceptable range of refrigeration.

6.5.3 All instrument information, calibration verification and environmental data should be documented on form G-201-F2 Calibration Certificate.

6.5.4 If a temperature device is removed from service for any reason including failed verification the device in the Calibration Schedule must be lined out with the notation "removed from service." The device is no longer permitted in GMP work areas.

6.5.5 For devices that pass verification a calibration sticker will be attached and the unit returned to service. Because this device has been internally calibrated, it cannot be used to verify calibration of other temperature sensing devices.

6.5.6 Some devices that have temperature read-outs are only for reference and must be noted as so. These devices are not to be used to record temperature and a

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secondary, traceable temperature reading device must be used for GMP activities.

7.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	05/25/10	Original	-	-
1	04/01/13	Changed the SOP format & number	13-249	B. Johns
2	06/24/15	Biennial review: Changed Title. Rewrote instructions for calibration verification. Added G-201, Calibration Program reference. Added use of traceable reference standards.	15-0560	B. Johns
3	04/08/19	Scheduled review: Added information about temperature monitors that are for reference purposes	19-0245	J. Maignan
4	10/20/23	Updated logo and format. Added information for inline devices.	CC-23-0520	B. Echevarria
5	12/12/23	Added quarterly thermometer challenges for QC Lab only.	CC-23-0599	J. Sassman