

	<b>Standard Operating Procedure</b> <b>Calibration Verification of Digital Humidity Indicators</b>		<b>SOP Number</b> <b>G-203</b>	<b>Revision</b> <b>3</b>
			<b>Effective Date</b> 06/11/19	<b>Page</b> <b>Page 1 of 3</b>
<b>Written by/ Date</b> <i>Jm 04/29/19</i>		<b>Reviewed by/ Date</b> <i>JE 05-01-19</i>		<b>Approved by/ Date</b> <i>Sevicki Seasonal 05/21/19</i>
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## 1.0 Purpose

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

## 2.0 Scope

This procedure is for the calibration verification of digital humidity indicating devices including data loggers and fixed humidity controlled devices with a humidity indicator (i.e. stability chamber). Some devices may also measure temperature which is not covered in this SOP. This SOP does not cover the calibration or repair of any humidity measuring device.

## 3.0 Responsibility

- 4.1 It is the responsibility of QC Laboratory Personnel to follow this procedure.
- 4.2 It is the responsibility of QC Laboratory Management to ensure the procedure is current and is being followed.

## 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 %RH – Percent Relative Humidity
- 4.7 QC – Quality Control

## 5.0 References

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5.1 G-201-F2, Form, Calibration Certificate

5.2 G-201,SOP, Calibration Program

## **6.0 Procedure**

6.1 Refer to SOP G-201 Calibration Program for calibration schedule and instructions on the documentation of the calibration verification.

6.2 It is recommended that fixed calibration hygrometers are replaced at least every five years. Hygrometers that can be calibrated should be verified or calibrated at an external calibration lab at least once every five years.

6.3 If an indicator fails internal calibration verification and the instrument is able to be calibrated the unit must be calibrated and recertified by an external laboratory before returning to service.

6.3.1 Exception: If the humidity indicator is a component of a larger piece of equipment and specific calibration instructions are available, the humidity indicator may be adjusted by personnel familiar with and qualified to perform the adjustment.

6.4 Verification Process:

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

6.4.2 Select a %RH as the reference point that pertains to the instrument being verified. For example: if the hygrometer is used at a controlled humidity, verify at a %RH within the controlled range.

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

6.4.4 The common specification for verification is +/- 5°C of reference %RH unless otherwise specified by the needs of the application or recommended by the equipment manufacturer.

6.4.4.1 For instruments such as stability chambers that have a digital readout of the humidity, the fixed humidity of the device can be manually adjusted to the fixed point setting 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.

- 6.4.5 The common verification cycle for hygrometers is 1 year.
- 6.4.6 If a hygrometer 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.
- 6.4.7 For devices that pass verification, a calibration sticker will be attached and the unit returned to service.
- 6.4.8 Some devices that have humidity read-outs are only for reference and must be noted as so. These devices are not to be used to record temperature and a 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	13-248	B. Johns
2	06/26/15	Biennial review: Changed SOP format. Rewrote SOP for calibration verifications.	15-0580	B. Johns
3	03/26/19	Scheduled review: Added information about humidity monitors that are for reference purposes	19-0243	J. Maignan