



Calibration Procedure

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1.0 PURPOSE

1.1 Describe the calibration and control procedure for all instruments used to test, measure, inspect or verify products and processes. Moreover, it defines the calibration program to follow for all instruments, loops and control systems.

2.0 SCOPE

2.1 Applies to all personnel responsible for the execution and verification of calibration procedures for measuring and test equipment.

3.0 REFERENCE/RELATED DOCUMENTS

3.1. Change Control and Preventive Maintenance Program

4.0 DEFINITIONS

Term	Description
Accuracy:	The ability of an instrument measurement to match the actual value of the quantity being measured. Accuracy is a function of precision and bias. The accuracy of an instrument is provided by the manufacturer according to specific requirements. Also, defined as the degree of conformity of a value indicated by an instrument compared to the value of a recognized standard or a true value. Accuracy is also known as the tolerance or uncertainty of the instrument. This is how much the value of an instrument can vary from a known value.
Accuracy Ratio (ART)	The reason between the accuracy of the instrument to be calibrated and the accuracy of the calibration standard (example, if the accuracy of the instrument is $\pm 1\%$ and that of the calibration standard is 0.1% , then the ART value is calculated as $.1 / .0.1$, which means that the accuracy of the standard is 10:1 or 10 times the accuracy of the instrument).
Calibration Alert Report (CAR):	A report generated when an instrument is found damaged or broken during scheduled and/or non-scheduled calibrations; is found overdue prior to performing a scheduled calibration or is not found during a scheduled or non-scheduled calibration. Damaged – An instrument that has visible damage. Broken – An instrument that is inoperative. Overdue – An instrument will be considered overdue if: Calibration is not performed or the instrument is not available.
Calibration Certificate (CC)- Work Order (WO):	A form generated to document the calibration data during a scheduled or non-scheduled calibration of an instrument. All WO or CC will have an assigned unique ID number.
Calibration Frequency:	The time interval, expressed in terms of months, in which an instrument is calibrated or inspected to assure that, is within the required operational parameters.
Calibration Laboratory:	Any in-house or outside organization that provides calibration services to the company.
Calibration Not Required:	An instrument that is used for reference only and is not associated with a measurement that will affect form, fit or function of a product or process.



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Term	Description
Calibration Range -	Minimum and Maximum Values to be checked during the instrument calibration.
Calibration Standard -	Reference equipment used to calibrate other instruments whose accuracy is equal to or greater than that of the instrument to be calibrated. Instrument to which we rely as true and reliable to calibrate other instruments.
Calibration Standard Operating Procedure (SOP):	The specific steps and operations to be followed by Calibration Personnel during calibration performance. All calibration procedures, acceptable for use, must be controlled and maintained through the company. approved document control system.
Calibration:	The comparison of an instrument or measurement standard of unknown accuracy to a measurement standard of known accuracy in order to detect, correct, report or eliminate by adjustment any variation in the measuring of the Unit Under Test (UUT).
CCMS	(Computerized Calibration Management System) – Acronym for the computerized system used for the management of calibration activities.
Consumable Items –	Tools that are routinely interchanged, damaged and scrapped because of the process in which they are used (ex. Forming wires, mandrels, conductivity / pH solution standards).
Critical Instrument:	An instrument used in manufacturing or utilities processes to measure, control or indicate the present value of a parameter in an operation that may directly affect product quality, purity, integrity, strength, identity and acceptance, and/or personnel safety and health.
Engineering Unit:	A system of measurements or set of units which is used to specify anything that can be measured. A system of measurements comprises a set of chosen base units, together with derived units determined by their defining equations and proportionality factors.
Instrument Calibration Failure Limit -	The limits set so that an instrument is deemed not to pass or calibration.
Instrument Range (Span):	The measurement range of an instrument. The instrument range is expressed in terms of engineering units, whenever possible, and is normally stated in terms of upper and lower limits, for example -4°F to 176°F. Also defined as the minimum and maximum values that the instrument is capable of measuring, receiving or transmitting with the accuracy and resolution specified by the instrument manufacturer design.
Instrument Tolerance:	The maximum acceptable limit of error that an instrument will not exceed when used under specified manufacturer conditions, including the effects of conformity, hysteresis, dead band and repeatability errors. An instrument tolerance is usually provided by the manufacturer.
Instrument:	Devices used to measure, test and/or inspect finished products or processes; to determine compliance with approved requirements.
Linearity:	The variation or difference between a known standard measurement and the full range of expected values.



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Looping -	Combination of two (2) or more instruments or control functions arranged so that signals pass from one to the other for the purpose of measuring and/or controlling a variable in the process.
Measurement Standard:	A material, instrument, reference material or system intended to define, realize, conserve, or reproduce a unit or one or more of a quantity to serve as a reference. These devices are used to calibrate instruments or other measurement standards and provide traceability. Also known as calibration standard or working standard.
New Instrument and Update Form:	A form used to update the status of existing instruments or to add instruments of a new or existing type to the calibration program.
Nominal Value:	A designated value from which actual values may vary.
Non-Critical Instrument:	An instrument used in manufacturing or utilities processes to measure or to indicate the present value of a parameter, in an operation that does not affect product quality and/or personnel safety and health.
Out of Tolerance (OOT) Report:	A report generated when an instrument is found out of the instrument tolerance/accuracy during scheduled or non-scheduled calibrations.
Out of Tolerance,	when the value provided by the instrument when compared to the value provided by the standard is found outside the established limits of acceptable calibration accuracy.
Precision:	The ability of an instrument to reproduce its own measurement; usually referred to as repeatability.
Process Alarm Range -	Specific range within which the process generates some signal or alert condition. In cases where alarm ranges are not defined, then the operational range of the process will be used.
Process Range:	The range in which a process parameter is considered acceptable, as per approved or validated requirements. The process range is expressed in terms of engineering units, whenever possible, and is normally stated in terms of upper and lower limits, for example 0°F to 80°F. The process range must be within the instrument range, at all times.
Product Assessment:	An evaluation or study of possible product impact, relating to production, research and development or validation data, due to an out of specification condition.
Resolution:	The ability of a measurement standard to detect and indicate small changes in the characteristic of the UUT measurement result. The resolution is usually given by the number of digits displayed in the instrument.
Reverse Traceability:	The ability to determine which instruments have been calibrated or inspected by a particular measurement standard.
Special / Limited Calibration:	A calibration within a limited range of what is specified by the instrument manufacturer or internal procedures.
Tolerance Limit:	The extremes of a designated range through which the measured value of characteristics may vary and still be considered acceptable.



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Traceability:	The ability to correlate individual measurement results, through an unbroken chain of calibrations, to one or more of the following: A) U.S. national standards maintained by the National Institute of Standards and Technology (NIST). B) Fundamental or natural physical constants with values assigned or accepted by NIST. C) National standards of other countries, which are associated, with NIST. D) Ratio type of calibrations. E) Comparison to consensus standards.
UUT	Unit Under Test
Working Standard:	Designated measurement standard used to perform field and laboratory calibrations.

5.0 EQUIPMENT AND INSTRUMENTS

- 5.1. The required standard references, and ancillary equipment necessary to perform each calibration will be based on the calibration to be performed. Describe the standard instruments to be used in Form C. - INSTRUMENT CALIBRATION INVENTORY LIST.
- 5.2. Also, describe all instruments to be calibrated in Form C. - INSTRUMENT CALIBRATION INVENTORY LIST.

6.0 RESPONSIBILITIES

6.1. Calibration Department

- 6.1.1. Ensure that all instrument calibrations are performed in compliance to the existing calibration SOP.
- 6.1.2. Ensure that all Calibration Personnel is trained in all required SOP before performing any assigned task.
- 6.1.3. Maintain the calibration SOP or manufacturer manuals necessary to perform the specific process for internal calibration of instruments.
- 6.1.4. Manage, control and maintain standards for calibration of designated instruments.
- 6.1.5. Maintain instrument calibration certification records ensuring appropriate traceability of the instrument.
- 6.1.6. Schedule calibration activities and notify Instrument Owners of calibration due dates for portable instruments.
- 6.1.7. Determine the calibration frequency and supporting rationale for all instruments.
- 6.1.8. Utilize approved external calibration services whenever an in-house calibration is not possible.
- 6.1.9. Physically identify calibrated instruments with a unique control number.



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- 6.1.10 Process New Instrument/Tool Notification and Update Form for the activation, inactivation, or status modification of instruments.
- 6.1.11 Generate OOT reports, for out of tolerance of critical instruments within 1 business day of detection.
- 6.1.12 Generate a CAR Calibration Alert Report for overdue, not found, broken or damaged instruments within 1 business day of detection.
- 6.1.13 Ensure all instruments that are out of tolerance, overdue, broken or damaged are properly labeled out of service and removed from the operational area, if possible until recalibration or replacement is completed.

6.2. Instrument Owner

- 6.2.1. Ensure all instruments are calibrated as required, prior to usage.
- 6.2.2. Arrange for instrument activation in the calibration program following the established requirements and providing all necessary technical documentation regarding the instruments.
- 6.2.3. Arrange for instrument inactivation in the calibration program by following the established requirements.
- 6.2.4. Notify the calibration department about any change in the instrument status (e.g. location, instrument parameters, owner) ensuring the necessary documentation is completed, as required.
- 6.2.5. Turn portable instruments to the calibration department, prior to the calibration due date.
- 6.2.6. Verify that there are no instruments with missing, damaged or expired calibration or inspection labels.
- 6.2.7. Conduct product assessment, when required, for OOT, overdue, broken or damaged instruments used in manufacturing, in conjunction with a QA Representative. Complete the product assessment within the required timeframe.
- 6.2.8. Complete an OOT or a CAR, within the required timeframe.

6.3. Quality Assurance (QA)

- 6.3.1. Determine in conjunction with the Instrument Owner, whether there is or not possible product impact, after an OOT and/or CAR.



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- 6.3.2. Determine whether an instrument is critical or non-critical based on the intended use and specifications.
- 6.3.3. Verify 'Instrument Parameters' are specified correctly based on the manufacturer specifications.
- 6.3.4. Support on the process range identification, according to process validation.
- 6.3.5. Support on the calibration frequency rationale and adequacy, based on the user requirements.
- 6.3.6. Approve all calibration documentation, as the final approver.

7.0 SAFETY AND ENVIRONMENTAL PRACTICES

- 7.1. All Calibration Personnel (internal and external) should follow the health, safety and environmental guidelines established by the company.
- 7.2. Internal calibrations shall be performed in a suitable environment to ensure an appropriate and accurate result.

8.0 PROCEDURE DESCRIPTION

8.1. Instrument Classification

- 8.1.1. All instruments entered into the calibration program must be classified as critical or non-critical, based on the intended use and the user requirements.
- 8.1.2. Critical instrument includes, but is not limited to:
 - An instrument in direct contact with the product or process.
 - An instrument used to monitor/document environmental conditions critical to the production process.
 - An instrument that is used for process control:
 - Used for cleaning and sterilization.
 - Prevents cross contamination.
 - Stores electronic data of systems used in *the* monitoring of critical parameters.
 - Monitors room air particulate.
 - An instrument used to measure raw materials.
 - An instrument used as standard.
 - Any other instrument so defined by Quality.
- 8.1.3. Critical and non-critical instruments used in the manufacture and/or testing of components or products or used as part of a process must be calibrated prior to use.



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8.2. Adequacy of Standards

- 8.2.1. All instruments should be calibrated with a traceable standard with an accuracy ratio of 4:1 or greater, whenever possible.
- 8.2.2. Standards must cover the range of intended use.
- 8.2.3. Only Calibration Technicians are authorized to use, handle and manage measurement standards used for calibration.
- 8.2.4. The standard storage area should have the appropriate facilities to avoid deterioration or damage of any standard or instrument. The standard storage area should be a secured room.
- 8.2.5. If a standard is found out of tolerance, the calibration department will generate an OOT and will perform a reverse traceability report, in order to verify that all instrument calibrated using the standard, are in compliance.

8.3. Registration of New Instrument and Update Calibrations Records- Form A

- 8.3.1. This form must generated by the Instrument Owner or designee to: activate, modify the status of, or inactivate instruments within the calibration program.
- 8.3.2. The calibration department should be consulted prior purchasing instruments that require calibration.
- 8.3.3. Controlled logbooks will be used to assign a unique ID number to all new instruments in the calibration program. Logbooks will be classified and labeled as follows:
 - Critical Instruments
 - Non-Critical Instruments
 - Calibration not required
- 8.3.4. All instruments will have a unique ID number consisting of a prefix followed by a sequential number. Instruments will be classified as follows;
 - Critical Instrument – for example, C-0001
 - Non-Critical Instrument – for example, NC-0001
 - Calibration not required – for example, NR-0001
- 8.3.5. The New Instrument and Update Calibration Form A is completed as follows:

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