Calibration and Calibration of pH Meter

B.Pharm.VI Sem (BP 606)

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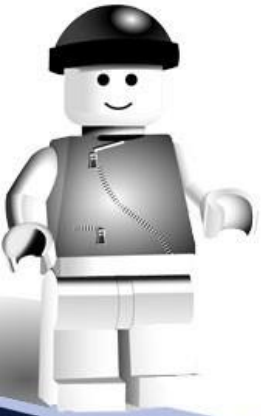
Introduction

“Automatic, mechanical, or electronic equipment or other types of equipment, including computers, or related systems that will perform a function satisfactorily, may be used in the manufacture, processing, packing, and holding of a drug product. If such equipment is so used, it shall be routinely calibrated, inspected, or checked according to a written program designed to assure proper performance. Written records of those calibration checks and inspections shall be maintained.”

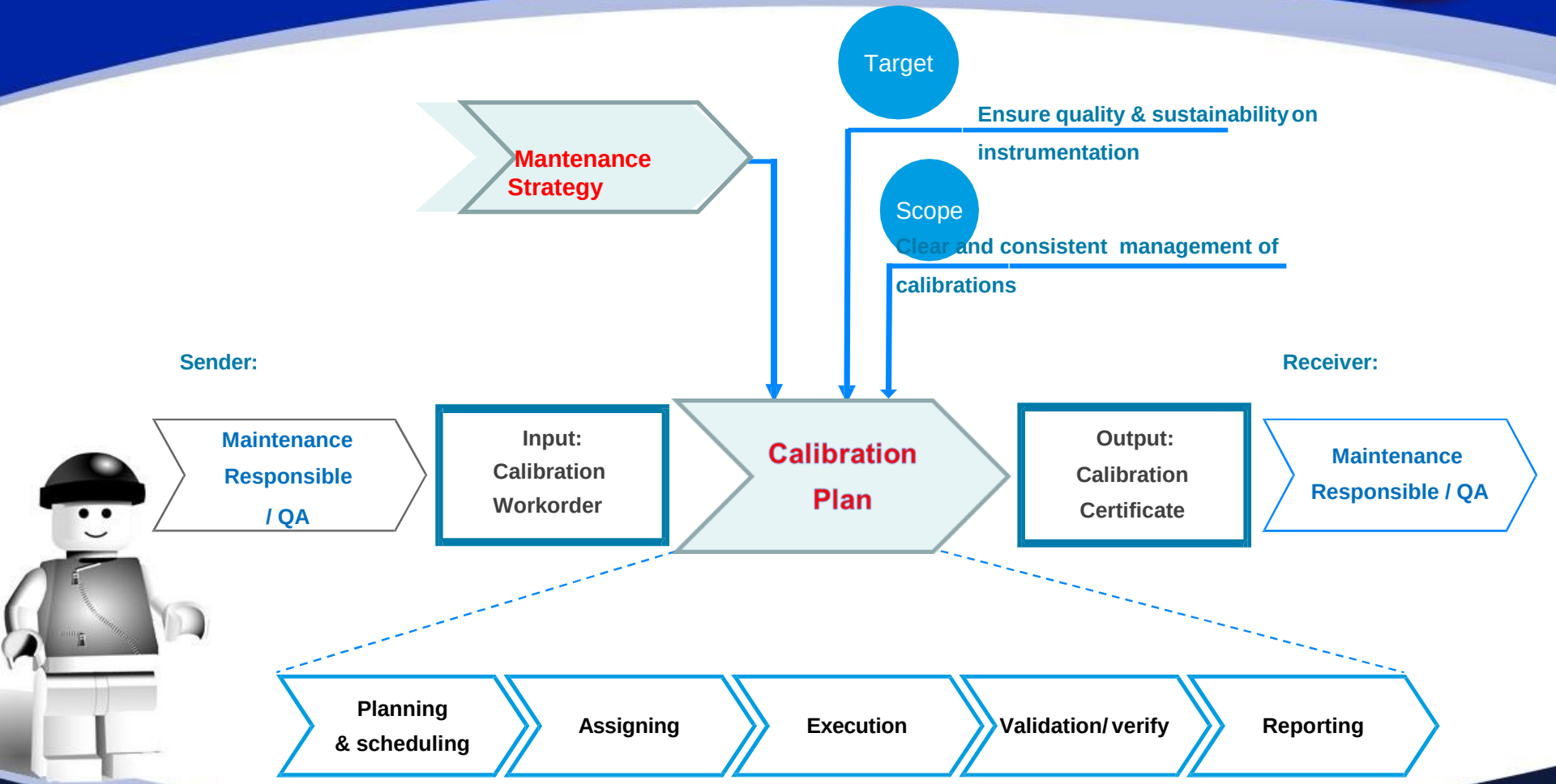
US Code of Federal Regulations, 21 CFR 211.68

Importance of Calibration

- Defining the rationale for equipment criticality designations and associated calibration intervals.
- Assigning responsibilities for equipment users, equipment managers, quality assurance personnel, and calibration vendors to help ensure company-wide consistency and regulation of your processes.
- Approving calibration vendors such that they are in compliance with the guidelines of your Quality System.
- Identifying and labeling equipment.
- Processing investigations of out of tolerance conditions and other calibration-related issues that may necessitate corrective action.
- Controlling and storing records, including calibration certificates, status change forms, and calibration SOPs.



Calibration master plan

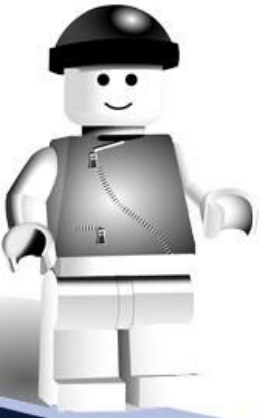


What is Calibration?

The process of comparing the response of some instrument or system to a standard instrument or system over some measurement range.

•To maintain the accuracy and precision of test equipment at all times.

•To ensure highest level of confidence in all measurement that affect materials disposition decision, with unbroken chain of traceability to national standard.



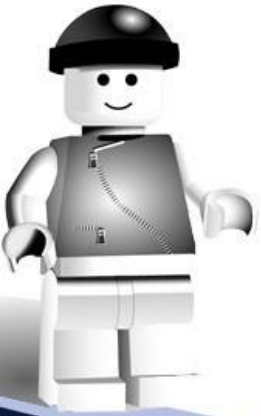
•To determine whether the equipment is still fit for its intended purpose.

•It is based on the comparison of a primary standard or instrument of known accuracy with another equipment (to be calibrated)

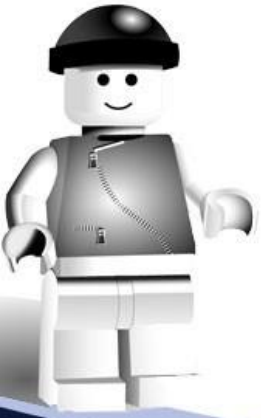
•It is used to detect, correlate, report or eliminate by adjustment of any variation in the accuracy of the equipment being calibrated.

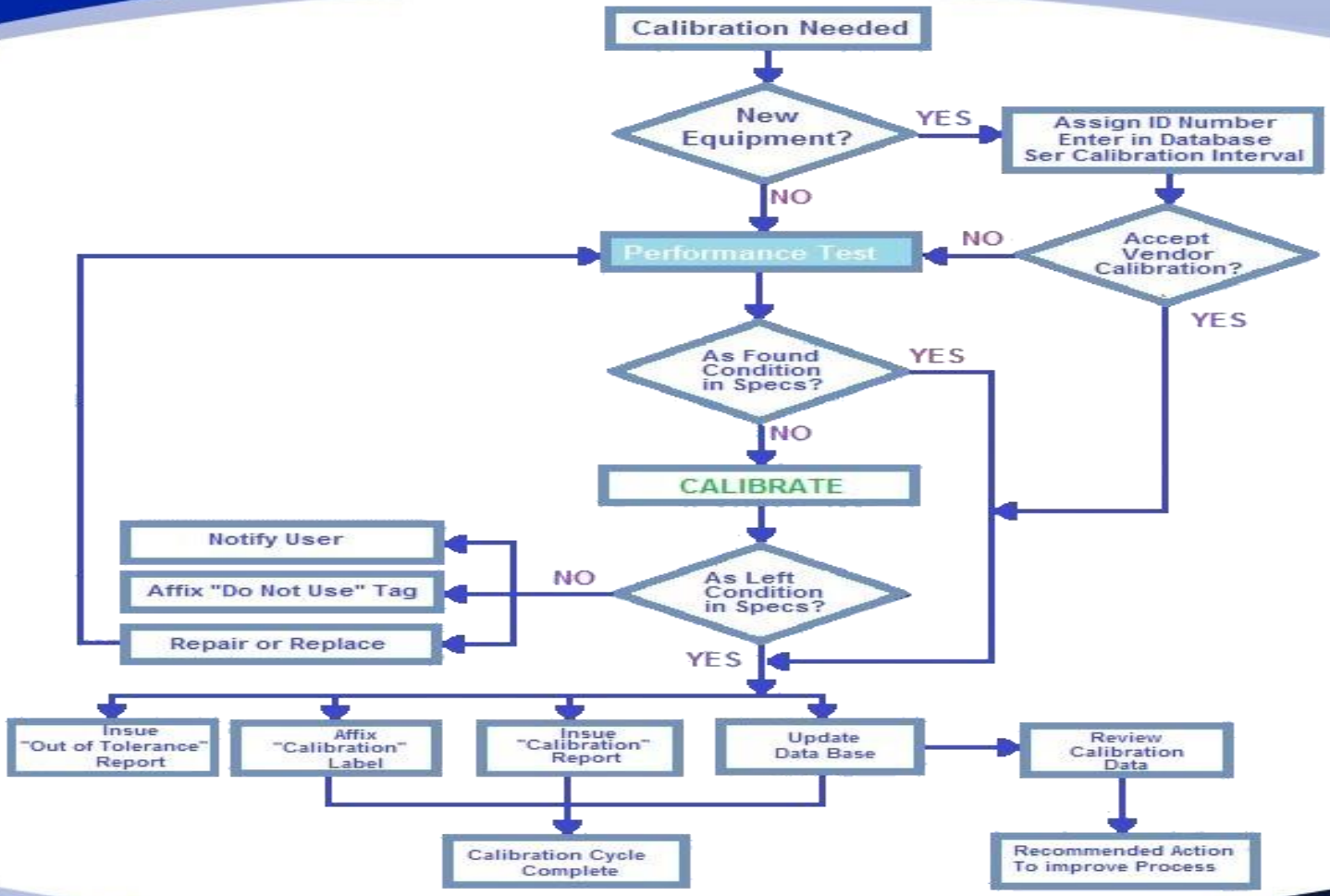
Why Calibrate?

- Components age and equipment undergoes changes in temperature or humidity or sustains mechanical stress, performance degrades. This is called drift. Then test results become unreliable. While drift cannot be eliminated, it can be detected and either corrected or compensated for through the process of calibration.
- Historical Issues
  - Cost, cost, cost
  - No clear goals
  - Limited technical oversight or understanding
  - Most staff afraid of it



Calibration Process

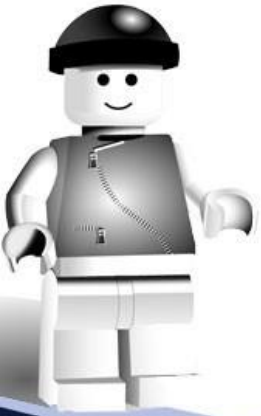




Calibration Process

MASTER INSTRUMENT LIST

- Serial Number
- Name of Instrument
- Location
- Accuracy Required
- Range of Measurement
- Calibration Done Date
- Due Date for Next Calibration
- Calibration Certificate Number & Date



Calibration Process

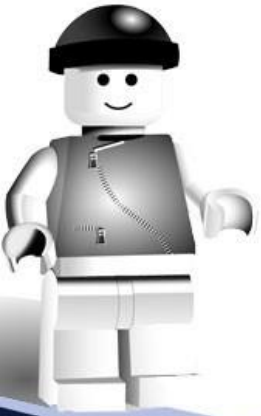
EQUIPMENT CLASSIFICATION

- Critical equipment:

  - Direct measurement that affect the final product quality
  - Measurement on critical process parameters in the process specification

- Non critical equipment:

  - Indirect measurement that will not directly affect the final product quality
  - Shall be maintained based on company maintenance schedule



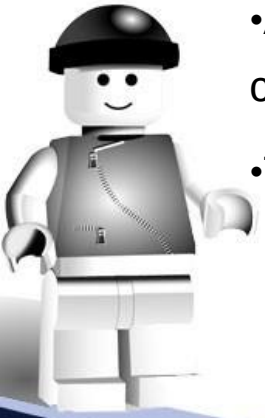
Calibration Process

VERIFICATION

Applicable to equipment that cannot be calibrated (adjustment, correlation, etc)

- Verification against measurement standard with correction factor documented
- Actual reporting of result shall include the correction factor
- Temperature correction factor "- 2 ^{0}C".
  - Measured value: 24^0 C
  - Reported value = 24 ^{0}C –2 ^{0}C= 22

^{0}C



OUT OF CALIBRATION

- Remove equipment from use
- Out of Calibration Investigation to be carried out to determine the source of inaccuracy
- Evaluate the impact of OOC result on the final product quality and other previously measured data
- All investigation findings should be documented

Calibration Process

CALIBRATION CERTIFICATE

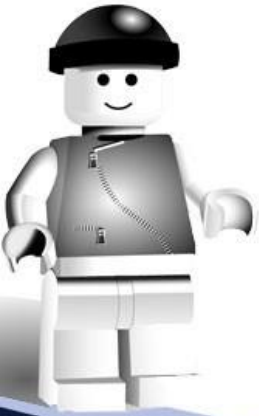
- Name and address of contracted calibration laboratory
- Name and address of client
- Description and identification of item calibrated
- Environment conditions when calibration was made
- Date of receipt of instrument, date of calibration and date of next calibration
- Calibration method
- Result of calibration
- Signature and title of person responsible for the calibration
- External calibration contract shall be awarded to Accredited by the nation institution

How can we improve and monitor the process?

Calibration Software?

YES….With specialist calibration management software the users can manages and stores all instrument and calibration data. The result is a streamlined, automated calibration process, which improves quality, plant productivity and efficiency.

Benefits of Using Calibration Software …. Procedures and calibration strategies can be planned and all calibration assets managed by the software. Position, device and calibrator databases are maintained, while automatic alerts for scheduled calibrations can be set up. The system no longer requires pens and paper. The software generates reports automatically and all calibration data is stored in one database rather than multiple disparate systems. . Calibration software has many functions that help in meeting these requirements, such as Change Management, Audit Trail and Electronic Signature functions.



EXPERIMENT NO. 1
Calibration of pH Meter

Introduction:

Electrochemistry is a branch of chemistry that deals with the linkage of chemical reaction and electricity. It often encompasses oxidation-reduction reactions. One feature of a Redox reaction is the transfer of electrons among the reactants and it can be carried out in an electrochemical cell in which the oxidizing agent is physically separated from the reducing agent by a salt bridge that maintains electrical contact between the two.

An electrochemical cell consists of two conductors called electrodes- an anode where oxidation occurs and a cathode where cathode occurs, which are immersed in an electrolyte solution. In potentiometric methods of analysis,electrochemical cell uses reference electrodes which potential is accurately known. Also, indicator electrodes are dipped in the solution of analyte and develop a potential that depends on the activity of the analyte.

A glass electrode is widely used indicator electrode for the hydrogen ion. It consists of a thin, pH- sensitive glass membrane sealed in a heavy walled glass or plastic tube. It has an internal Ag/AgCl reference electrode. pH meters are so selective that it only responds to the activity of the hydrogen ion.

Many industries uses high class pH meters for the analysis and quality control of many consumer products, analysis of blood gases which indicates some of diseases, monitoring pollutants and many other more.

Objectives:

Turn on the pH meter on and wash with distilled water.

Immerse the electrode in pH 4 buffer solution and press 'standardize' button after the reading has been stabilized

Wash the electrode with distilled water and gently dry with tissue.

Repeat the procedure for the pH 7 and pH 10 buffer solutions.

II. Determination of pH/ Electric Potential (mV)

Prepare three sachets of different brands of hair conditioners

In three separate beakers, dissolve the samples in 100 ml water.

Dip the first solution to the electrode.

Record the reading in pH and in mV

Wash the electrode with distilled water. Gently dry it using a tissue.

Dip the second solution and repeat the procedure for the remaining analytes.

Using the measured electrode potential, calculate the concentration of H^+ in the solution

Discussion:

The calibration of the pH meter followed a stern procedure. The electrode must first be washed free of contaminants by distilled water and dried gently by a tissue paper. The buffer with pH of 4 is read, and then the buffer with pH of 7 and 10 followed. Readings of the electrode must first be stabilized before recording them to obtain accurate data.

The table above shows the readings of pH meter. L'Oreal has a pH of 3.74. Palmolive has 8.84 and Pantene has a pH of 3.82.

Conclusion:

Analysis showed that the measured pH of the three conditioners has slight deviations to the calculated pH when the potentials of the buffer solutions are considered.

Percent Errors of the pH are the following: 0.538% for L'Oreal, -1,285% for Palmolive and 0.262% for Pantene conditioner.

Errors may be accounted from personal errors due to the preparation of the solutions. Since the conditioners are emulsions, they are not that very soluble in water which causes unconformities in the reading of the glass electrode.

Thank you