

STANDARD OPERATING PROCEDURE

Title: Instrument Calibration Management System

Effective Date: _____

Approvals (Signature and Date):

Responsible Department Head

Technical Authority

QA/QC Manager

1. PURPOSE

- 1.1 To define the requirements necessary to develop and maintain a program used for calibration to assure that applicable measuring and test equipment is calibrated and maintained within specified accuracy limits. This system is required to assure the suitability for use of test and measurement equipment used to determine the acceptability of a material, product, test or process and the suitability of the environment in which samples are produced, tested or stored.

2. SCOPE

- 2.1 This program covers the calibration and tracking of automatic, mechanical and electronic equipment used in development, production, environmental control, and testing of products. It applies to, but is not limited to, R&D, Manufacturing, Facilities, Product Engineering, and QA/QC.

3. TERMINOLOGY AND DEFINITIONS

3.1 Terminology and Definitions

- 3.1.1 Accuracy: See Instrument Accuracy.
- 3.1.2 Active: An Instrument with an Active status is currently being tracked and calibrated as per this SOP. It is in calibration and cleared to be used on GxP and other processes. An Active instrument is identified with a current Calibration label.
- 3.1.3 As Found Data: As found data consists of the instrument reading, the standard reading and the error between the two for each calibration point before any adjustments to the instrument are made.
- 3.1.4 Audit: A comparison of the Calibration History Files information to the Calibration Management System's Data Base information to verify accuracy.
- 3.1.5 Calibration: To check, adjust or systematically standardize the graduations of a quantitative measuring instrument to a known standard of greater accuracy.
- 3.1.6 Calibration Class: A classification given an instrument to help identify the instruments importance to the process and or equipment.
- 3.1.7 Calibration Control Number (CCN): A four digit number assigned to each instrument that uniquely identifies it in the Calibration Management System (CMS). The CCN's are in no significant order other than the next available number is assigned as the instruments are entered into the CMS. Once a CCN is assigned to an instrument it is never used again, it is as unique to that instrument as a serial number. This number may be used as the instruments serial number if there is no manufacturer's serial number.

- 3.1.8 Calibration Frequency: How often an instrument is calibrated. (i.e. Calibration Frequency = 12 months, the instrument is calibrated at minimum, every 12 months). Also see section 12.
- 3.1.9 Calibration History File: A file containing the Instrument Review Forms, Calibration Reports, and all other forms and reports associated with a single calibrated instrument. This file is identified by CCN and can be found in the Calibration Section of the MEF. See Section 11.1.
- 3.1.10 Calibration Label: Labels used to identify the instrument and its current calibration status. Also see section 6.2.
- 3.1.11 Calibration Management System (CMS): A computerized system set up and maintained by Facilities to assure that instruments and process control equipment are calibrated at planned intervals. Also see section 8.
- 3.1.12 Calibration Point: Each place that an instrument is checked or adjusted along its Calibration Range.
- 3.1.13 Calibration Range: The range or span over which an instrument is to be calibrated. This range may or may not be the full range the instrument is capable of measuring, indicating, or transmitting.
- 3.1.14 Calibration Standard (Standard): Calibration Standards are of the highest accuracy in a calibration system. These standards are used in the calibration of other instruments as the reference to which they are compared. Calibration Standards are traceable to the National Institute of Standards and Technology (NIST), natural physical constants, or another recognized agency (i.e. the International Organization of Legal Metrology "IOLM"). Also see Section 6.1.
- 3.1.15 Calibration Status: There are 3 calibration status classes: Active, Inactive, and Retired. See their definitions.
- 3.1.16 CMS: See Calibration Management System.
- 3.1.17 Contact Person: The Contact Person is the supervisor of the department of which the instrument is a part. This person is responsible for receiving and signing all required reports and forms as outlined throughout this procedure. This person is also the main contact for scheduling calibrations and any other interaction with the Facilities Department for calibration purposes.
- 3.1.18 Corrected to Data: Corrected to Data consists of the instrument reading, the standard reading and the error between the two for each calibration point after any adjustments to the instrument are made.
- 3.1.19 Error: The difference between a single instrument reading and a standard value as determined by Standard Reference Instrument (Standard), expressed in engineering units.
- 3.1.20 Frequency: See Calibration Frequency
- 3.1.21 Function: See Instrument Function.
- 3.1.22 Grace Period: A time period in which a calibration may go past due without being considered past due. Also see section 13.
- 3.1.23 Inactive: An Instrument that has been assigned a CCN but is not currently being tracked or calibrated. It is not considered calibrated and can not be used on GxP or other processes. This instrument is fully functional. It just needs to be calibrated and re-activated. An Inactive instrument will be labeled DO NOT USE. NOTE: A DO NOT USE label may be used on a Retired or Inactive broken instruments also. An exception to this is an instrument once

tracked as a Calibration Class 1 or 2 instrument then changed to a Calibration Class 3 instrument. This instrument is considered Inactive as far as calibration scheduling is concerned but is labeled and used as described in section 3.2.3.

- 3.1.24 Instrument: A device for recording, measuring, controlling, or used for reference (SRM). Gauge Blocks, optical Standards, etc. are considered to be instruments to alleviate identification problems.
- 3.1.25 Instrument Accuracy: The plus and/or minus range between the reading of an instrument and the true value of what is being measured that the manufacturer guarantees the instrument to be within at all times.
- 3.1.26 Instrument Function: A description of what the instrument is going to be used for that will help identify it's the unique use.
- 3.1.27 Instrument Range: The full range an instrument is capable of measuring, indicating, or transmitting.
- 3.1.28 Process Limits: The maximum acceptable error of an instrument based on the demands of the process.
- 3.1.29 Repeatability: The difference between repeated instrument measurements under identical process conditions at different times, expressed as a percentage of full scale.
- 3.1.30 Resolution Increment: The smallest graduation that is readable on an instrument.
- 3.1.31 Retired: An instrument that is retired is broken and no longer able to be used. This instrument is not tracked or calibrated. This instrument is labeled DO NOT USE and/or is thrown away. (Before an instrument can be thrown away, approval must be given. See section 11.8)
- 3.1.32 Standard: See Calibration Standard 3.1.14.
- 3.1.33 Standard Reference Materials (SRM): Materials for which a high certifiable level of quality exists, allowing these well characterized materials to be used in user standardization activities.
- 3.1.34 Standardized: See User Standardized.
- 3.1.35 Tolerance: See Process Limits.
- 3.1.36 Trackability (Traceability): Documentation which shows an unbroken chain of comparison between the test instrument and an accepted standard of accuracy (i.e. National Institute of Standards and Technology, a natural physical constant, or other recognized agency).
- 3.1.37 Transfer Standard: An instrument that is calibrated by a Calibration Standard and shows it trackability through the Calibration Standard. Calibration Standards are traceable to the National Institute of Standards and Technology (NIST), natural physical constants, or other recognized agency (i.e. the International Organization of Legal Metrology "IOLM").
- 3.1.38 Units: The engineering units used to describe what the instrument is measuring, indicating, or transmitting.
- 3.1.39 User: See Contact Person.
- 3.1.40 User Standardized: An instrument that has its calibration and or linearity checked and possibly corrected by the user.

3.2 CALIBRATION CLASSIFICATIONS

- 3.2.1 CALIBRATION CLASS 1: An instrument in development, manufacturing or utility processes for the purpose of indication, signal transmission, automatic control, record keeping, alarming, or other purposes which may directly affect the quality of the product. QA/QC must be notified and a DR may be initiated if one of these instruments is found outside of Process Limits. This instrument is identified by a blue Calibration Class 1 label or by the Calibration Class 1 box checked on the User Standardized or Limited Calibration Labels. See section 6.2.3 and Attachment A, Figures 3, 7, and 8.
- 3.2.2 CALIBRATION CLASS 2: An instrument used in development, manufacturing or utility processes for the purpose of indication, signal transmission, automatic control, record keeping, alarming, safety, maintenance, operator convenience, efficiency, or other purposes which does not affect the operation of the process or the quality of the product. This instrument is identified by a green Calibration Class 2 label or by the Calibration Class 2 box checked on the User Standardized or limited Calibration Labels. See sections 6.2.4, 6.2.6, 6.2.7 3.2.4 and Attachment A, Figures 4, 7, and 8.
- 3.2.3 CALIBRATION CLASS 3: An instrument that is not critical or is on non-critical equipment. It is used only for indication and is not required to be calibrated on a regular basis. This instrument is calibrated initially, calibration is then required only on request there after. The initial calibration must be accurate to plus or minus 10% throughout the full span or throughout the used range of the instrument. This Instrument is identified by an orange Calibration Class 3 label. See section 6.2.5 and Attachment A, Figures 5 and 6.
- 3.2.4 LIMITED CALIBRATION: An instrument that is only required or can only be calibrated at one point or at a very narrow range. This classification falls under Calibration Classes 1 or 2. This instrument is only certified at that one point or at that narrow range. If that point or range is to be changed, the instrument must be re-calibrated. This instrument is identified by a purple Limited Calibration label. See section 6.2.6 and Attachment A, Figure 7.
- 3.2.5 USER STANDARDIZED: An instrument which is standardized by the user before every use, or at some user-defined period. The instrument is calibrated at its assigned interval by the Facilities Department for linearization of the instrument. This classification falls under Calibration Classes 1 or 2. This Instrument is identified by a yellow User Standardized label. See section 6.2.7 and Attachment A, Figure 8. A white and yellow Standardized label may also be present, see section 6.2.10 and Attachment A, Figure 12.
- 3.2.6 CALIBRATION NOT REQUIRED: In certain applications or because of the nature of the instrument, there are instances that calibration is not required. These instruments are identified by a white and blue Calibration Not Required label. See section 6.2.8 and Attachment A, Figures 9 and 10.
- 3.2.7 DO NOT USE: An instrument that is malfunctioning, broken or if the instrument has been removed from the calibration schedule (Inactive) and must be calibrated before it is used again This instrument is identified by a red Do Not Use label. See section 6.2.9 and Attachment A, Figure 11.

4. RESPONSIBILITY

- 4.1 The Facilities Department shall be responsible for the following:
 - 4.1.1 Developing and administering the Calibration Management System (CMS), including maintaining instrument calibration history files and data base to demonstrate trackability of calibrations to the National Institute of Standards and Technology (NIST) or other recognized agency.
 - 4.1.2 Maintaining working and calibrated Calibration Standards for calibration of designated instruments.

- 4.1.3 Writing and executing the SOP's for calibration of designated instruments.
- 4.1.4 Defining the Process Limits, Calibration Class, Calibration Frequency, Calibration Range and Instrument Function for specified processes in conjunction with the user.
- 4.1.5 Selecting reputable calibration contractors and verifying appropriate standards and documentation are provided. Calibration contractors are supervised by the Facilities Department
- 4.1.6 Notifying Materials Management of new calibration contractors to be added to the approved suppliers list.
- 4.1.7 Auditing Calibration History Files.
- 4.2 The QA/QC Department shall be responsible for the following:
 - 4.2.1 Assist in defining the Calibration Class, Calibration Frequency, Instrument Function, Calibration Range, and Process Limits for specified processes and lab instruments in conjunction with Facilities when needed.
 - 4.2.2 Auditing the calibration program as part of the internal audit program.
- 4.3 Departments shall be responsible for the following:
 - 4.3.1 Notifying Facilities via a New Instrument Calibration Request Form , section 11.2, when a new instrument has arrived.
 - 4.3.2 Defining the Calibration Class, Calibration Frequency, Instrument Function, Calibration Range, and Process Limits for specified process and lab instruments in conjunction with the Facilities Department.
 - 4.3.3 Ensuring that an instrument has an appropriate and valid calibration label attached prior to its use.
 - 4.3.4 Monitoring an instrument's performance and requesting out of cycle calibration and/or adjustments to Calibration Frequency, when appropriate.

5. REFERENCES AND APPLICABLE DOCUMENTS

- 5.1 National Conference of Standards Laboratories (NCLS), Medical Products and Pharmaceutical Industry Calibration Control System Guidelines, 1986 Revision.
- 5.2 Managing the Metrology System, C. Robert Pennella, 1992, ASQC Quality Press Publications.
- 5.3 Instrumentation, Franklyn W. Kirk and Nicholas R. Rimboi, American Technical Publisher, Third Edition.
- 5.4 Instrument Society of America (ISA) Engineers Instrumentation Reference 10th Edition and Standards & Practices for Instrumentation, 10th Edition.
- 5.5 Equipment Monitoring, Repair and Preventative Maintenance, Documentation Basics That Support Good Manufacturing Practices. Carol DeSain, 1993, Aster Publishing Corporation
- 5.6 Master Procedures, Paul L. Simmons, 1990, ICT
- 5.7 Recommended Practice: Medical Products and Pharmaceutical Industry Calibration Control System, RP-6, July 10th, 1986.
- 5.8 09-0010-SOP-1.0, "Supplier Qualification and Auditing Procedure"

5.9 11-0061-SOP-1.0, "Preventive Maintenance Program"

5.10 11-0079-SOP-1.0, "General Calibration Protocols"

5.11 11-0080-SOP-1.0, "Vender Calibration"

5.12 12-0026-SOP-1.0, "Master Equipment Files"

6. MATERIALS AND EQUIPMENT

6.1 Standards

6.1.1 CCN numbers 0000 through 0199 are reserved for Calibration Standards. If an instrument is assigned one of these numbers it will adhere to the requirements outlined in this section, Standards

6.1.2 Calibration Standards are the instruments of the highest accuracy in a calibration system.

6.1.3 Standard Reference Materials (SRM) are considered standards when assigned an Standard CCN Number

6.1.4 Calibration Standards should maintain an accuracy ratio of 4-1 over the instruments Process Limits they are being used to calibrate.

6.1.5 Calibration Standards are traceable to the National Institute of Standards and Technology (NIST), natural physical constants, or other recognized agency (i.e. the International Organization of Legal Metrology "IOLM").

6.1.6 An instrument that is calibrated with a Calibration Standard may be used to calibrate other instruments as long as it adheres to the requirements outlined in this section, Standards. This instrument is called a Transfer Standard.

6.1.7 Calibration Standards are kept in a controlled area of the Facilities Department and are only to be used for calibration by authorized personnel.

6.2 Calibration Labels (Attachment A)

6.2.1 Calibration labels are to have all sections completed and are to be affixed on or as close to the instrument as possible. If possible, avoid affixing the calibration label to a removable part of the instrument such as a cover. For protection, a clear plastic overlay will be placed over the written information. This will prevent the information from being worn off, cleaned off, wiped off, or from being changed.

6.2.2 Calibration Control Number (CCN), Attachment A, Figures 1 and 2: This is a gray label with black type (2 sizes). This label is used to identify the instruments Calibration Control Number (CCN). This number is to be written in the place provided with a black permanent marker.

6.2.3 Calibration Class 1, Attachment A, Figure 3: This is a blue label with black type. This label is used to indicate the calibration date, the calibration due date, the CCN and the calibration technician of an instrument defined as Calibration Class 1 that is not User Standardized or its calibration is not limited.

6.2.4 Calibration Class 2, Attachment A, Figure 4: This is a green label with black type. This label is used to indicate the calibration date, the calibration due date, the CCN and the calibration technician of an instrument defined as Calibration Class 2 that is not User Standardized or its calibration is not limited.

- 6.2.5 Calibration Class 3, Attachment A, Figures 5 and 6: This is a orange label with black type (2 sizes). This label is used to indicate the calibration date and the calibration technician of an instrument defined as Calibration Class 3.
- 6.2.6 Limited Calibration, Attachment A, Figure 7: This is a purple label with black type. This label is used to indicate the calibration class, calibration date, the calibration due date, the CCN and the calibration technician of an instrument that's calibration is limited.
- 6.2.7 User Standardized, Attachment A, Figure 8: This is a yellow label with black type. This label is used to indicate the calibration class, calibration date, the calibration due date, the CCN and the calibration technician of an instrument defined as User Standardized.
- 6.2.8 Calibration Not Required, Attachment A, Figures 9 and 10: This is a white label with blue type (2 sizes). This label is used to indicate the date of placement and the assigning calibration technician of an instrument that does not require calibration.
- 6.2.9 Do Not Use, Attachment A, Figure 11: This is a red label with black type. This label is used to indicate the date of placement and the assigning calibration technician of an instrument that is in need of repairs or calibration.
- 6.2.10 Standardized, Attachment A, Figure 12: This is a white label with black type with a yellow stripe through the 'Standardized' section of the label. These labels are used by the user to track the standardizations of User Standardized instrumentation. This label is not required. It is used by the user as a tool for standardization date references.
- 6.2.11 Calibration Seal, Attachment A, Figure 13: This is a black and blue seal. It is placed across where two parts of an enclosure comes together. This seal is to prevent unauthorized personnel from opening an enclosure and or tampering with the calibration settings. If this seal is broken, calibration is no longer valid. This seal is used at the discretion of the calibration technician.
- 6.2.12 These Labels are custom and are purchased from ABC Products Inc. (800) 555-1234. Because they are custom, they have no part number, they are identified as the XYZ Corp Calibration Labels. Their specifications are kept by Ampac in the XCY Corp customer file.
- 6.2.13 See Attachment S, for discontinued Calibration Labels. These Labels are valid and may still be seen on instrumentation.

7. HEALTH AND SAFETY CONSIDERATIONS

- 7.1 Follow the recommended safety precautions when servicing each instrument as described in maintenance and calibration standard operating procedures for individual instruments or systems.

8. CALIBRATION MANAGEMENT SYSTEM DATA BASE

- 8.1.1 Facilities shall utilize a database with pertinent information for each instrument and standard. This database shall contain, but will not be limited to the following:
 - Information on all Instruments that are calibrated on a routine basis.
 - Information on all Instruments that are used as Standards
 - The ability to generate Calibration Reports. Sections 11.5, 11.6
 - The ability to generate custom instrument lists. Sections 11.11-11.17
 - The ability to sort instruments to given criteria.
 - The ability to generate Due for Calibration Lists as well as Past Due for Calibration Lists. Sections 11.13- 11.15.
 - The ability to recall instruments which have been calibrated with a particular standard. (reverse traceability). Section 11.17.

9. CALIBRATION SCHEDULING SYSTEM

- 9.1 All Calibration Class 1 and Calibration Class 2 instruments must have their calibration current before a system or instrument is utilized in a GxP process.
- 9.2 Calibration of instruments shall be staggered to avoid an overload in any given time period.
- 9.3 Instruments shall be scheduled for calibration according to development and production availability.
- 9.4 Each Contact Person will receive at the beginning of each month a Due for Calibration by Department List, see section 11.13. This list outlines calibrations that are due in their area for the coming month.

10. DESCRIPTION OF CALIBRATION STANDARD PROCEDURE

- 10.1 Prior to initiating any calibration activities, the individual performing the calibration shall review the instrument's calibration file, operation manuals, and the SOP which describes the calibration procedure for the instrument.
- 10.2 Calibration shall be performed using suitable standards at a minimum of three operating points divided over the instrument's operating range (typically 0 - 50 - 100%), with the exception of those instruments which are operated within a limited range or at a single point. These instruments shall be calibrated within the limited range or at the single point, as appropriate.
 - 10.2.1 Additional calibration measurements may be made to assure linearity and/or repeatability.
 - 10.2.2 An instrument found to be outside of its Process Limits shall be adjusted to be within tolerance, if possible.
 - 10.2.3 An instrument does not have to be outside of Process Limits for adjustments to be made. Adjustments may be made to improve accuracy.
 - 10.2.4 If a Calibration Class 1 instrument is found to be outside of its Process Limits, Proper notification must be made as per section 11.7.
 - 10.2.5 If a Calibration Class 2 instrument is found to be outside of its Process Limits, Proper notification must be made as per section 11.7.
 - 10.2.6 An instrument that is found to be outside of its Process Limits and cannot be adjusted to within specification shall be tagged with a red "DO NOT USE" label as per section 6.2, and the proper notification must be made as per section 11.7.
- 10.3 Calibrations shall only be performed by authorized and trained personnel or an approved calibration contractor.
- 10.4 Calibration readings for all instruments shall be recorded on the Calibration Report. For calibrations performed by outside contractors, the information may be recorded on the contractor's standard forms with a Calibration Report attached as a cover sheet referencing the contractor's report.
- 10.5 Initial calibration of instruments required for use in new development or manufacturing processes or applications which do not have established calibration procedures may be accomplished using the manufacturer's recommended procedure together with 11-0079-SOP-1.0.
- 10.6 Instruments shall be calibrated using an appropriate calibration SOP or using the manufacturer's recommended procedure and practices with 11-0079-SOP-1.0. If there are no manufacturer's recommended procedures, and there is no applicable existing SOP, then an appropriate SOP shall be written.