1. **Purpose**

This document defines the policies and procedures for calibration and preventive maintenance (PM) activities. These policies and procedures include identification, calibration and preventive maintenance procedures, and impact assessment of all tools and equipment associated with the calibration and preventive maintenance programs.

1. **Scope**

Calibration applies to measurement equipment/tools utilized in production and product acceptance activities while preventive maintenance applies to any process equipment and infrastructure that impact product quality. Any measurement equipment/tools not utilized in acceptance activities are exempt from the calibration program. Any infrastructure or equipment that does not impact product quality is exempt from preventive maintenance.

1. **General** 
   1. **Definitions** – N/A
   2. **Responsibilities**

**Quality** – Quality Management is responsible for the implementation and continued compliance with the procedures specified in this document and by the regulatory authorities.

* 1. **Equipment and Materials** – N/A
  2. **Safety Precautions** – N/A
  3. **Training Requirement** –Quality personnel shall be trained to the procedures specified in this document.
  4. **Record Management** – All Calibration and PM records are managed and maintained by the Quality Department.
  5. **Reference Documents and Materials**

**21 CFR 820** – FDA Quality System Regulations

**SOR/98-282** – Canadian Medical Device Regulations

**MDR 2017/745** – EU Medical Device Regulation

**MDD 93/42/EEC** – EU Medical Device Directive

**ISO 13485** – Medical Device Quality Management Systems

**ISO 10012** – Measurement Management Systems

**QP-0007** – Identification and Traceability Process

**QP-0008** – Nonconforming Product Process

1. **Calibration and Preventive Maintenance Procedure**

The calibration and preventive maintenance programs utilize the following procedures to achieve conformity of product to determined requirements. The calibration program includes monitoring and measurement equipment/tools needed to provide evidence of product conformity to requirements. The PM program includes infrastructure and process equipment utilized in the production of product.

The company document procedures for the validation of the application of computer software used for calibration or preventive maintenance. Applicable validations are be completed prior to implementation and/or after changes to the software or its application. The specific approach and activities associated with the software validation and revalidation shall be proportionate to the risk associated with the use of the software, including the effect on the ability of the product to conform to specifications.

* 1. **Identification**

All equipment, tools, infrastructure, etc included in the calibration and preventive maintenance programs shall be assigned a unique identification number. These ID numbers are maintained within the associated program and utilized to link the item to the required and completed activities. Where possible, labels shall be attached the items that include the following information:

* Identification Number
* Name of Item
* Date of Last Calibration or PM Activity
* Due Date of Next Required Activity
  1. **Calibration and Preventive Maintenance Procedures**

All calibration and PM activities shall follow documented procedures. These procedures are specific to the type of equipment, tool, etc and shall include specified intervals for completing calibration or PM activities. The intervals shall be adjusted as necessary in response to the results of the activities. Calibration activities shall be traceable to national or international measurement standards; where standards do not exist, the basis for calibration shall be recorded. Records of the calibration and PM activities shall be maintained and include the equipment identification, date of service, the procedure followed, individual that completed the activity, and test/inspection data.

Calibration procedures shall be established to verify the accuracy and precision of equipment around the range of values the equipment is intended to measure. The preferred methodology includes verifying a low, mid, and high point at the range of interest. A minimum of a low and high point verification is required for calibration.

When calibration and/or prevent maintenance activities are completed externally, a certificate of calibration and/or PM shall be received, reviewed, and approved. All other above requirements and records remain applicable.

In the event an item is found out of specification and cannot be returned to working condition, the item shall be removed from operation and either scrapped or labeled appropriately to prevent inadvertent use. Any necessary adjustments or re-adjustments shall be documented.

* 1. **Impact to Product Assessments**

Any equipment, tool, etc that is found to be out of specification during calibration and/or PM activities shall initiate an assessment of the validity of the previous measurement results and/or outputs in regards to product impact. The assessment and any appropriate actions taken shall be completed and recorded within the Nonconforming Product Process (QP-0008) and traceable to the Calibration and PM Programs.

1. **Revision History**

| **Rev #** | **Doc #** | **Effective Date** | **CHO** | **Description of Change** |
| --- | --- | --- | --- | --- |
| 01 | QP-0014 |  |  | Initial implementation of the Calibration and Preventive Maintenance Process |