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How to Set Up a Pipetting Quality Control Program for Your Lab

Improve the Quality of Pipetting and Reliability of Results

Abstract

Calibration, maintenance, and regular control of tools are essential to ensure the highest quality standards of laboratory work. For pipettes, the best practice would be to do calibration and maintenance according to the manufacturer's recommendations at least annually or biannually, as well as implement a program for regular testing of pipette performance during use and between calibration intervals. This practical guide outlines the requirements for in-lab testing program, as well as for professional calibration and maintenance services.

Introduction

Many quality systems and standards, such as Good Laboratory Practice (GLP), Good Manufacturing Practice (GMP), and the ISO 9000 series require that a regular, documented maintenance and calibration procedure must be in place for all instruments. Some labs, especially accredited laboratories, also require regular calibration of pipettes in ISO 17025 certified accredited calibration facility due to the security and traceability of results it brings. The good quality program of pipettes is a combination of regular day-to-day in-house checks and regular professional calibration and maintenance.

Pipette Quality Control Program

To meet the regulatory and quality system requirements, laboratories should have in place a documented program for pipette quality control during use. A suggested program based on best industry practices consists of the following elements:

- In-lab testing routine, with pipette performance checked in-lab regularly, such as daily, weekly or monthly
- Regular calibration and maintenance of pipettes performed at an accredited service laboratory, annually, biannually or every 3 – 4 months.

In-Lab Testing Routine

In-lab testing routine includes a regular checking of all pipettes in the laboratory for their systematic and random error.

1. What Should Be Done?

The pipettes are checked using a balance or a photometer and the systematic and random errors are calculated from the results, compared against acceptance limits, and recorded. This testing can be done by the actual users of the pipettes, but the results should be checked and documented by an independent party, such as quality management personnel.

2. How Often?

The testing frequency is based on the risks associated with the use of the pipettes—the testing interval should be in ratio with the amount of work you can afford to lose if you find the pipettes are out of specifications. Practices used in various labs differ greatly, but a common testing routine is monthly or weekly, sometimes even daily. Pipettes should also be checked each time after autoclaving pipettes or pipette parts. Performance check is also needed if a pipette is dropped or if physical damage is suspected.

3. What is Needed?

For In-lab testing, you will need the following items:

- 4- or 5-decimal balance with pipette calibration setup such as evaporation trap, or a photometer system
- Software for calculating and recording results
- Disposable tips, the same type as used with the pipettes when in use
- De-ionized water or dye solutions if photometric measurement is used
- Thermometer and barometer
- Standard Operating Procedure document describing the in-lab testing routine and the procedure for dealing with pipettes that do not meet the acceptance criteria

4. What Acceptance Criteria Should Be Used?

The pipettes should be checked at 1–2 volumes, with 4–10 measurements each. The systematic and random error should be compared against the limits defined either by pipette manufacturer or ISO 8655.

5. What are the Outcomes of the Testing?

The in-house testing routine should provide the following deliverables:

- Documented history of all the pipettes showing their testing interval, testing dates, and at minimum the result if they met the acceptance criteria or not
- The pipettes not meeting acceptance criteria should be clearly marked and removed from use, and forwarded to maintenance and calibration to resolve the issue

Calibration and Maintenance Program

Most laboratory quality systems require a regular calibration and maintenance program for pipettes. Today, laboratories commonly use an external service provider for this labor-intensive work that requires highly sophisticated quality systems.

1. What Should Be Done?
The pipettes should be maintained according to the manufacturer's instructions regularly. The maintenance consists of the cleaning and greasing of pipettes, as well as replacement of wearable parts. Alongside maintenance, the pipettes should have their performance verified by calibration—measurement of systematic and random error along with any necessary adjustments.

2. How Often?
The testing frequency is based on the risks associated with the use of the pipettes. The maintenance interval is affected by such factors as pipetting frequency, liquids used, and the age and model of pipette. A minimum maintenance interval of one year is suggested, with calibration done annually or more often, such as every 3–6 months. If, for example, volatile liquids or solvents are used, maintenance should be done more often.

3. What is Needed?
For a full maintenance and calibration of pipettes, the calibration laboratory used should have at minimum:

- Full ISO 8655 compliance, including controlled environment in terms of temperature, vibration, and humidity
- Accreditation according to ISO 17025 standard with traceability of measurements to international standards
- Balances with a minimum of 5- and 6-decimals along with evaporation traps or draft shields
- Software for recording results
- Professionally trained technicians | engineers who understand pipette technology and good pipetting practices, as well as requirements set by regulatory and quality systems

4. What Acceptance Criteria Should Be Used?
The pipettes should be measured at 2–3 volumes, with 4–10 measurements each, with systematic and random error calculated and compared against the acceptance limits. The limits defined in ISO 8655 or by the manufacturer of the pipettes are suggested.

5. What Are the Outcomes of the Calibration?
The calibration and maintenance program should provide at minimum:

- Documented records of all maintenance and repair activities done to the pipettes
- Calibration certificates showing the identification of the pipettes, such as serial numbers and time of calibration, tips used, measurement conditions, measurement equipment and personnel
- Random error and systematic error should be calculated and documented, along with acceptance criteria such as pass | fail limits

Best Practices for Setting up the Pipetting Quality Control Program

To work according to Good Laboratory Practice, a Standard Operating Procedure (SOP) for Pipette Quality Control should be defined. Below are areas that should be described at minimum in the SOP to guide laboratory personnel through the process:

1. For in-lab testing routine, define:
   a. Testing frequency
   b. Testing equipment and environment
   c. Personnel qualifications to conduct testing
   d. Measured volumes and aliquot quantities
   e. Acceptance criteria
   f. How to record and store the results
   g. Actions of isolating and marking pipettes not meeting acceptance criteria
   h. Procedures for evaluating the effect of failure on the work performed with the pipette in question

2. For maintenance and calibration program, define:
   a. Requirements for a calibration laboratory, ISO 8655 and ISO 17205 at minimum
      i. Testing equipment, environment, and procedures
      ii. Qualifications for maintenance and calibration personnel
   b. Calibration and maintenance frequency
   c. Decontamination procedures for the pipettes before maintenance
   d. Volumes tested and number of measurements
   e. Acceptance criteria
   f. Recording and documentation systems
   g. Actions of isolating and marking pipettes not meeting acceptance criteria
   h. Procedures for evaluating the effect of failure on the work performed with the pipette in question

3. For continuous education of laboratory personnel, define:
   a. Training program for personnel on correct pipetting techniques and ergonomics
   b. Training on quality systems and standards related to pipettes and pipetting
   c. Documentation and qualification plans for personnel training

Summary

Pipettes are precision tools that have significant influence on results of scientific experiments. All laboratories working with pipettes should have in place a regular program for not only calibration and maintenance but also regular in-lab testing of pipettes, using qualified personnel and correct equipment for all work. To implement this quality program, the program should be documented and controlled with Standard Operating Procedures for laboratory personnel. The SOP should cover all aspects of the program, including the continuous training of personnel on pipettes and pipetting.

Do you need support in pipette service and maintenance? Contact Sartorius for a Pipetting Academy training at www.sartorius.com/pipetting-academy

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