Maintenance and Issuing Inspection Records for Micropipettes

Keywords: JCSS, validation, GLP/GMP, SOP, ISO8655, leak tester, accuracy tester, routine check, routine examination

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1. Introduction

This document discusses methods of management for pipettes used in research.

○JCSS has not yet established a system for pipettes and there are currently no recognized national standards. As a result, commercially available pipettes are mainly validated by pipette manufacturers, pipette sales agents, and maintenance companies that have pipette measurement services. This means that currently each organization has its own validation certification.

○These practices are equivalent to pipette users and sellers creating their own management standards and using procedures that follow those standards for inspection and management.

○Furthermore, each pipette manufacturer determines the contents (specifications) of its micropipette records and does not consider the management values required for the locations where the pipettes are used. As a result, they uniformly require levels of “accuracy” and “repeatability” that pipette users do not need.

○Pipette manufacturers have changed the structure of newer pipettes so that users can perform maintenance themselves and they recommend this to users.

Based on these conditions, we offer the following management methods to more efficiently manage micropipettes onsite, with the goal of improving productivity in research fields through improved accuracy in analysis and reduced equipment management time. Furthermore, the method allows users themselves to uniformly manage pipettes from various manufacturers and reduce the time and expense required for conventional pipette maintenance.

2. Proposal

○This proposal covers the onsite maintenance and regular inspection of pipettes.

○For performance testing and accuracy inspection, we recommend the AD-1690 pipette leak tester and the AD-4212-PT pipette accuracy tester, which employs gravimetric methods regulated by ISO8655, respectively.

3. Management practices

○Use a leak tester to confirm whether pipette maintenance is necessary. A leak test for one unit takes about 6 seconds.

○If a leak is found, maintenance is necessary. Follow the instruction manual to perform repairs at the level of part exchange. After repair, use the leak tester to check that the leak has been stopped.

○If an accuracy test is required, use the AD-4212-PT. The volume setting and number of repeated measurements can be freely determined. Furthermore, the required specifications can be determined by the tester. The included WinCT-Pipette software can be used to easily print the results. By including

required management items in the data output and managing the files, this method can be used for paper-based GLP/GMP or SOP certification.

○The procedures above can guarantee validation of the site.

Glossary

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JCSS

JCSS stands for Japan Calibration Service System, which is a system run by the National Institute of Technology and Evaluation (NITE) to register calibration laboratories.
NITE investigates the quality system, calibration methods, estimates of uncertainty, facilities, and other factors of registration candidates to determine their appropriateness as a calibration laboratory. After registration, calibration laboratories can issue calibration certificates with the JCSS logo.
A calibration certificate with the JCSS logo guarantees traceability to the national measurement standards of Japan, and certifies the proficiency of the calibration laboratory.
However, as of June 2010, JCSS has not established standards nor registered any calibration laboratories with regards to pipettes.

Validation (confirmation of qualification)

The validation process verifies that procedures, products, testing methods, etc. provide expected results in medical supply manufacturing, quality control, etc.The acquisition of documented, expected results is verified using documented methods and the results are recorded.
The expected results are the performance and functioning required of equipment. Confirmation of acquisition of expected results by equipment has three steps: confirmation of installation qualification (IQ), confirmation of operational qualification (OQ), and confirmation of performance qualification (PQ).
When using pipette accuracy testers, the mass of distilled water output is converted to a volume and it is necessary to convert with water temperature and atmospheric pressure as functions. For this purpose, confirmation of qualifications when using the gravimetric method requires the following three items.

1. A balance to measure mass of distilled water
2. A thermometer to measure temperature of distilled water
3. A barometer

Since pressure changes have an unusually small effect on measurement results, it is acceptable to use a representative value (fixed value) for the location and it is not necessary to administer any new equipment. This means that validation of a pipette accuracy tester involves confirmation of the qualification of the balance and thermometer. Customers can download the sample forms required for the confirmation of qualifications free of charge from the A&D website and then administer the forms themselves. A&D also offers services to perform these confirmations[1].

Since use of a pipette accuracy tester involves use of a personal computer, computer validation may be investigated. Pipette accuracy testers are designed to check the operation of pipettes (apparatus) and do not provide direct guarantees for medical supply manufacturing or clinical results. Furthermore, the establishment of computer validation requires labor and money. Due to these and other points, we recommend managing measurement results using paper-based records.

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[1] In Japan

GLP/GMP

In order to sell new medical supplies and food products, it is necessary to submit test data to each country in advance. The accuracy of the data that makes up these submissions is verified by a system of controls known as Good Laboratory Practice (GLP, regulations for the safety testing of medical supplies), which targets research and development fields.
Meanwhile, the manufacturing and quality control of medical supplies and food products are regulated by Good Manufacturing Practice (GMP, standards for the manufacture and quality control of medical supplies).
Employing these quality control standards in an in-house system requires adjustments to the equipment used so they perform within self-appointed standards, as well as the periodic inspection of equipment and the recording of results.
Leak testers and pipette accuracy testers can confirm the correct functioning of pipettes and results can be recorded on paper.
Pipette accuracy testers are composed of an electronic balance and thermometer. The correct operation of each piece of equipment can be verified and recorded using the validation forms on our website.

SOP

SOP stands for standard operating procedure. Standard operation procedures specify standards for working conditions, procedures, management methods, and work guidelines in the manufacturing process with the objective of manufacturing products of a prescribed quality.

For example,
1. Before you use a pipette, check for leaks using a leak tester.
2. Perform regular checks of pipette accuracy using a pipette accuracy tester.
Since users can regulate accuracy and determine a pass or fail, A&D’s pipette accuracy testers make it possible to manage pipettes at the accuracy level required for the site.

ISO8655

This international standard collects general requirements for piston-operated volumetric apparatus (pipettes, burettes, diluters, etc.). ISO8655-2 regulates the requirements for pipettes and ISO8655-6 regulates gravimetric methods (methods to convert the distilled water output from a mass to a volume).
Japan Industrial Standards (JIS) has Regulation JIS K0970 for push-button microvolumeters (pipettes). However, many pipettes are made outside of Japan and most pipette manufacturers perform inspections using procedures based on ISO8655.