Scotland and Northern Ireland EQA Scheme in General Histopathology

EQAM08

MANAGEMENT OF SUPPLIES AND EQUIPMENT

ISO 17043:2010 ref	4.2
LOCATION OF COPIES	Q-Pulse (Electronic Master) Master Copy held by Quality Manager Standard Operating Procedures – Scottish Pathology Network
AUTHORISED BY	Dr. Geraldine O'Dowd - Scheme Chairperson 

Review and Amendment History			
Date Reviewed / Amended	**Version Replaces**	**Pages Changed**	**Details of review/Amendment**
Feb 2021	1.0	2 Pages (Front & 2)	Updated location of copies (front pg), added: Table of Contents (pg2)

Table of Contents

1 RATIONALE

The purpose of this procedure is to describe the management and selection of any suppliers and/or equipment to the scheme.

2 REFERENCES

- NHST, Code of Corporate Governance Section F [Standing Financial Instructions] Section 13
- Procedure for Visits to NHS Tayside Premises by Company Representatives
- QAA018 'Validation & Verification Policy'

The above documents must be read and understood before carrying out this procedure.

3 DUTIES, RESPONSIBILITES AND AUTHORITY

The Executive Team of the scheme are responsible for the implementation of this procedure and ensuring the Standing Financial Instructions are followed in accordance with NHS Tayside's Code of Corporate Governance.

4 SELECTION OF A SUPPLIER

When introducing new or updated suppliers or equipment, there must be a robust evaluation of the new product or service which demonstrates that it is fit for the purpose for which it is intended.

Validation: confirmation through the provision of objective evidence that the requirement for a specific intended use or application has been met.

Verification: confirmation through the provision of objective evidence that specified requirements have been fulfilled. Otherwise referred to as "Acceptance Testing".

5 APPLICATION

The procedures described in this policy will be used in the following situations:

Equipment Acceptance Testing: All new equipment which has been previously validated for intended use by the manufacturer, shall be verified before "live" use, to ensure that it meets the appropriate requirements. This process will also be relevant when equipment has been modified, serviced or moved.

Verification (Acceptance Testing) of Supplier: If a supplier has previously been validated and is used within the department in a way that does not deviate from the original protocol, it must still be verified before "live" use to ensure that it meets the appropriate requirements.

Validation of Supplier: All examination procedures that are developed, "in house" or those that are subject to modification from their original format or intended use will be validated before "live" use to ensure that it meets the appropriate requirements.

This policy provides the framework to enable to production of written logs documenting the method of evaluation, the outcome, the decisions taken and the individuals responsible.

6 PROCEDURE FOR VALIDATION

6.1 Identify Performance Characteristics

Provide a list of the known / expected abilities and properties of the equipment or supplier in question.

These can be gained from manufacturer's instructions or other published sources.

6.2 Identify Acceptance Criteria

Define the purpose and objectives of the validation / verification process. The project leader will identify what the object in question is desired to achieve. These criteria can be divided into those that are essential or those that are desirable.

It is these acceptance criteria that the performance characteristics of the object in question will be tested against to ensure that it is appropriate to requirement.

6.3 Document Results

Consider the format the results will be recorded in. It may be necessary to design worksheets that capture all of the information as the study progresses, including comments by staff.

6.4 Document Conclusion

Compare results with expected values to determine whether or not the method is suitable for use. This may include comparison with the performance of existing methods or information provided by the manufacturer.

Document a conclusion based on the analysis of the results.

6.5 Validation Sign Off and Approval

The project lead will review the data and complete the validation report (Appendix 1). They will then sign the validation section to authorise use.

7 ADVERSE EVENT REPORTING

Any methodology failures attributed must be raised as a CAPA and the Root Cause investigated. If the supplier or manufacturers are found to be at fault they must be informed and the communication recorded within the CAPA. The criteria for such an event includes the following:

- Ability to supply the service required
- Previous experience / company reputation
- Cost
- Delivery time
- Availability
- Customer service
- After-sales service
- Published evaluations

8 APPENDIX 1

Validation / Verification Report

Name of Procedure:

Performance characteristics:

Acceptance Criteria:

Validation / Verification method:

Relevant SOPs	
Number	**Title**

Relevant COSHH and Risk Assessments	
Number	**Title**

Results:

Conclusions:

Does the method/product meet the specified performance characteristics? ☐ Yes ☐ No

CA/PA:

Validation Authorisation Section

This procedure is suitable for diagnostic use:

☐ **Yes**

☐ **No**

Signed (Project Leader) _____ **Date** _____

Signed (Project Manager) _____ **Date** _____

Introduction of this procedure is authorised:

☐ **Yes**

☐ **No**

Signed (Service Manager) _____ **Date** _____

Signed (Quality Manager) _____ **Date** _____