

The Walton Centre NHS Foundation Trust
The Neuroscience Laboratories

SOP Title: Implementation of New Equipment/Method

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1. Introduction

When new equipment is received in the laboratory the following protocol should be followed to ensure that the equipment is set up correctly, safe to use, recorded correctly and all are trained in the proper use and maintenance. This process also applies to equipment on loan within the department. A similar procedure is adopted for the implementation of a new method which may or may not involve the introduction of a new piece of equipment.

Prior to new equipment being purchased or a new method being introduced within the department including the Liverpool Neuroscience at the Walton Centre (LNBW), a procurement process will have been followed as detailed in the Trusts Corporate Governance Manual. The process regarding the selection of Laboratory equipment and suppliers is detailed in the SOP DSG10 Selection, Management and Monitoring of Suppliers, Consumables and Equipment.

A member of staff will be assigned as responsible for the implementation of a new piece of equipment or procedure. This person is responsible for carrying out the actions set out in this SOP. This ensures the performance of all necessary implementation steps within target timescales

The purpose of this document is to provide guidelines on how implementation should be performed.

2. References

Number	Type	Title
DSHS32	Departmental\SOP\Health & Safety	Disinfection/Decontamination Procedure
DSQ20	Departmental\SOP\Q Pulse	Document Control of External Documents on Q Pulse
DCOM1	Training and Competency\Departmental\Competency	Competence and Competency Assessment Policy and Procedure
DP20	Departmental\Policy	Validation and Verification of Examination Procedures Policy and Procedure
DD78	Departmental\Document\Templates	Analytical SOP Template
DD41	Departmental\Document\Templates	SOP Template - The Neuroscience Laboratories

DRA10	Departmental\Document\Templates	Risk Assessment Template
DSHS13	Departmental\SOP\Health & Safety	Compiling MSDS and COSHH Assessments
DSG10	Departmental\SOP\General	Selection, Management and Monitoring of Suppliers, Consumables and Equipment
DSG17	Departmental\SOP\General	Consultation and Communication with Service Users
DP31	Departmental\Policy	Equipment Calibration and Metrological Traceability
DP8	Departmental\Policy	The Neuroscience Laboratories Document Control Policy
DSG16	Departmental\SOP\General	Procedure for Equipment Servicing and Dealing with Failures
DP20	Departmental\Policy	Validation and Verification of Examination Procedures Policy and Procedure
DSG10	Departmental\SOP\General	Selection, Management and Monitoring of Suppliers, Consumables and Equipment
DSG23	Departmental\SOP\General	Personnel Management and Records SOP
DSG16	Departmental\SOP\General	Procedure for Equipment Servicing and Dealing with Failures

WCFT Standing Financial instructions (section 12.3 and 12.4).
 WCFT Risk Management Strategy
 WCFT COSHH Policy

Related Area of Standards

ISO 15189\Technical Requirements\ISO 5.3 Laboratory Equipment, Reagents and Consumables

HTA\HTA PFE5 - Equipment is appropriate for use, maintained, quality assured, validated and where

appropriate monitored

ISO 20387:2018\6. Resource Requirements\6.5 Equipment

3. Grade of Operator

This SOP is for use by senior members of laboratory staff.
The member of staff assigned as responsible for the implementation of a new piece of equipment or method is responsible for carrying out the actions set out in this SOP.

4. Method

A member of staff must be assigned as the lead person responsible for the implementation of each new method or piece of equipment. This lead is responsible for completing the Equipment Implementation action plan on Q Pulse, deciding what actions need to be taken and when by, delegating any actions as necessary, reporting on progress at the relevant forum and ensuring the implementation process meets target dates set.

The following steps should be taken for the implementation of new equipment or new method:

Supplier Selection/Business Case

Before the purchase/introduction of any new methods or equipment, it may be necessary to consult with service users to determine the need for the new method – see DSG17 Consultation and communication with service users.

Once a need has been established, appropriate suppliers should be selected of either equipment or reagents. See SOP DSG10 Selection, Management and Monitoring of Suppliers, Consumables and Equipment. Selection of suppliers should be recorded in the appropriate form in appendix 1 of DSG10.

Feedback from service users and the outcome of the supplier selection can then supplement the creation of a Summary Business Case which is submitted to the procurement team initially and then the appropriate Trust committee to agree any associated costs/funding.

1. A Trust Summary Business Case must be completed by the departmental lead for the implementation of the new method/equipment in conjunction with an Executive lead.
2. The Summary Business Case should then be sent to the division's procurement team for review.
3. The Summary Business Case is then presented to the Trust Capital Monitoring Group where the case will either be accepted or rejected.
4. If the case is rejected, further work may be required based on the feedback given.
5. If the case is accepted, it is then submitted to the Executive board for final approval.

6. The Neuroscience Laboratories should then place any necessary orders on the e-procurement system.

Laboratory Modifications

1. Following the order being placed for a piece of equipment, the department may be informed of a delivery/installation date. In anticipation of this delivery and installation, any modifications required to the laboratory should be arranged. This may need to be in conjunction with a representative from the company supplying the equipment and our estates department.
2. The introduction of a new method may also require modifications to the laboratory.
3. Modifications may range from creating space for the equipment/removing shelving to a full survey of infrastructure and utility supplies.
4. Any modifications requiring the assistance of estates should be logged with the Estates and Purchasing helpdesk with timescales given to ensure the work is completed before installation.

Receipt and Installation of Equipment

1. When new equipment is delivered to the department it will be accompanied by a delivery note. Check that the items listed on the delivery note tally with the items actually delivered. The condition of the equipment should also be checked and any problems identified should be reported immediately to the procurement department. This may be done by The Neuroscience Labs staff or a representative from the supplier. If the items tally and there are no problems identified with the condition of the equipment, accept delivery by signing the delivery note. Place this in the delivery note tray in the Pathology office for receipting on e-procurement.
2. Equipment should be unpacked carefully, following any instructions which are supplied.
3. All electrical equipment should be Portable Appliance Tested (PAT) for safety before use. This is requested through the Estates and Purchasing helpline.
4. Equipment may then either be installed by The Neuroscience Labs staff or a representative from the supplier depending on the type and complexity of the equipment.
5. If the equipment is installed by a representative from the supplier obtain a copy of their installation record. This should provide information on equipment set up and any installation checks or tests they have performed to ensure the equipment is correctly installed.

Registration of Equipment

1. All new equipment should be registered on Q Pulse in the Assets module. This provides the department with a full list of equipment held. The Assets module also allows for the

inclusion of information including purchase and replacement dates, servicing and calibration details and any non-conformities associated with the equipment.

2. Equipment should be registered on Q Pulse as follows:

- a. Log onto Q Pulse as per SOP Logging onto Q Pulse.
- b. From the 'Launch Pad' select the 'Assets' module.
- c. A list of all the assets within the department will appear. To register a new asset, select either: -
 - 'File' then 'New Asset'OR
 - The 'New Asset' icon at the top left hand side of the screen.
- d. A new asset record will appear. The record should then be completed as fully as possible with the following information:

Number: This is a unique number assigned to the piece of equipment. It may be the number assigned by EBME or the Medical Devices department or if the asset does not have one of these numbers, it is assigned an unknown (UNK) number. To find the next UNK number, refer back to the full asset list in Q Pulse and click on the 'Number' heading at the top of the list. This puts all the asset numbers in sequence. Scroll to the bottom of the list and take the next number in the UNK sequence.

Asset Type: From the drop down list, select the asset type. If the asset type does not appear in this list, type in the asset type and tab across to the next box. The asset type will automatically be added to the list.

Serial Number: Enter the serial number of the asset.

Owner: From the drop down list, select the owner of the equipment. This is usually the Chief BMS/Clinical Scientist in each area.

Location: Select the exact location of the asset from the drop down list.

Description: Enter a brief description of the asset including model number. Also indicate here if the piece of equipment is critical within the LNBW – that is equipment with the potential to impact on the quality of the biological material and associated data.

Manufacturer: Select a manufacturer from the drop down list. If the manufacturer is not present in the list, enter the name and tab to the next box. The name will automatically be added to the list.

Available: Select yes.

Associated Documentation: Add a record of any associated documents by selecting the box with 3 dots and searching for the document. This should include cross

reference to instruction manual for the equipment which should also be recorded on Q Pulse as per SOP DSQ20 Document control of external documents on Q Pulse.

Department: Select which department the asset belongs to from the drop down list.

Further information must also be added to the asset record. Select the 'View/Edit Properties' icon at the top of the screen. The 'Additional fields' screen will appear. Within this screen enter:

Purchase Date: Using the calendar function.

Cost: Approx. cost of asset in the first box and the currency in the second box from the drop down list. This will usually be GBP.

Replacement Date: Enter the month and year the asset is due for replacement. Check with the Laboratory Manager when equipment requires replacement. This will depend on the type of equipment.

Date of entering into service: This is the date that the equipment was first used for analysing samples.

Condition when received: The condition when received e.g. New/Second hand/Reconditioned/Damaged etc.

3. As outlined in the Trust's Standing Financial instructions (section 12.3 and 12.4), the Trust is required to maintain an accurate Asset Register to help ensure the security of its fixed assets with a purchase cost of £5K or more. Upon receipt into the Trust, the Finance department will automatically add the equipment to the Trusts Asset Register if greater than £5k so no further action is required by Neuroscience Laboratories staff.

Training

1. Initial training may be provided by the suppliers depending on the type of equipment or procedure. This may be provided to all relevant staff or just staff responsible for the validation/verification of the new methods or equipment. A record of this training should be recorded in the New Equipment/Method Training Log – see appendix 1.
2. Once the equipment and/or procedure has been validated/verified for use and procedures established, training should be cascaded to all other relevant staff. Again a record should be kept of this training using the New Equipment/Method Training Log in appendix 1. The training log should then be included in the Equipment Implementation plan in the CA/PA module of Q Pulse.
3. Once initial training has been completed, competency must be demonstrated as part of the relevant competency assessments – Please refer to DCOM1 Competence and Competency Assessment Policy and Procedure.

Validation /Verification

1. All new equipment and all new methods should be validated and verified before being accepted into routine use. For full details, please refer to DP20 Validation and Verification of Examination Procedures Policy and Procedure. Dependant on equipment type and use, appendix 2 contains a template which can be used.

Standard Operating Procedures

1. SOPs should be written for the use of the equipment and/or the new method, giving full details and referencing any instructions as required. SOPs should be written using the correct template. All analytical SOPs should be completed using DD78 Analytical SOP Template which describes the requirements for completion of each section. Non-analytical SOPs should be completed using DD41 SOP Template.
2. SOPs should be incorporated into Q Pulse for document control purposes. This allows for authorisation and distribution to relevant staff. See DP8 The Neuroscience Laboratories Document Control Policy.
3. Once new SOPS have been authorised and the new equipment/method is fully implemented, make obsolete any relevant documents associated with any old equipment/methods.

Risk/COSHH Assessments

1. Any risk assessments associated with the new equipment/method should be performed and recorded using DRA10 Trust Risk Assessment template and following the Trusts Risk Management Strategy.
2. COSHH assessments should also be performed on any relevant substances associated with the method. Refer to DSHS13 Compiling MSDS and COSHH assessments and the WCFT COSHH Policy.
3. Both documents should be placed in Q Pulse and authorised and distributed appropriately.

Service User Communication

It may be necessary to inform our service users, both internal and external of any changes associated with the introduction of the new method/equipment. The requirement for this should be decided on a case-by case basis dependent upon the impact of the new equipment/method. The process of communication should follow DSG17 Consultation and communication with service users.

Extension to Scope

UKAS must be informed of equipment/method changes that significantly affect the scope of work. This depends on the type of equipment/method change. For example, new equipment such as a balance or freezer will not affect the scope however, a new analyser or analysis method would. Discuss all changes and additions of equipment and methods with the Quality & Governance Manager as early as possible in the purchase/implementation stage. A plan for informing UKAS and arranging assessment will be determined if required. It may be

necessary to remove the tests associated with the equipment/method from scope until assessed.

Applicable new equipment/methods will then be assessed by UKAS including all associated implementation documentation and validation/verification work. A decision will then be made regarding the accreditation status of the test. If accredited, the new equipment/method will be included in the departments scope of work.

Maintenance, Servicing and Calibration Requirements

1. On-going maintenance, servicing and calibration requirements of the equipment should be determined.
2. Day to day maintenance requirements should be incorporated into the SOP and be included in any training in the use of the equipment.
3. External servicing requirements should be determined. Refer to DSG16 Equipment Servicing and Dealing with Failures SOP for details of how to establish a service contract and how to manage planned preventive maintenance (PM) visits in Q pulse.
4. Some equipment may also require regular calibration. Refer to DP31 Equipment Calibration and Metrological Traceability SOP for details of how to establish and record calibrations within Q Pulse.

Disposal of old Equipment/Reagents

1. Once the new equipment/method has been fully introduced into the department, the old equipment and any associated old reagents should be disposed of.
2. Contact the Purchasing and Supplies department and request a Transfer/Disposal/Condemnation form. The Purchasing and Supplies department will then arrange disposal of the old equipment according to any associated regulations. Indicate on the Asset on Q Pulse that it is no longer available. The equipment will also be removed for the Trusts asset list.
3. Ensure equipment is appropriately disinfected before disposal – see DSHS32 Disinfection/Decontamination procedure.
4. Review the old reagents for disposal and their associated MSDS and determine the best course of action for disposal.

Equipment Implementation Action Plan

The various actions taken during the implementation of new equipment/method should be recorded. This is done within the CA/PA module of Q Pulse and allows for the inclusion of actions taken, dates actions performed and attachment of important documents.

1. CA/PA module of Q Pulse, select File>New>From Template and select Equipment/Method Implementation.

2. In the first section complete:

- CA/PA Type - select New Equipment/Method from the drop down list.
- Owner - choose the member of staff responsible for implementation and performance of actions.
- Details - provide information on the equipment/method to be implemented.

3. In the next section complete:

- Raised By and Against from the drop down list.
- Severity with -.
- Resolution and Root Cause with New Equipment/Method.

4. Several tabs are then available for completion with each tab listing a number of actions to be performed. As each stage of the equipment purchase/method implementation is performed, actions should be completed within the New Equipment/Method Implementation Record, adding a Response, Owner and Closed Date.

5. Once all actions in a tab sections are completed, it may be closed by entering the Owner, Completed By and Closed Date.

6. Documents may be added to the New Equipment/Method Implementation Record in the properties section including equipment requirements/specification, business case and service user communication.

7. Finally, the method/equipment implementation should be authorised. This action should be completed by a member of staff with the appropriate authority.

8. Once all actions are completed, the New Equipment/Method Implementation Record may be closed by the owner.

5. Appendix 1 – New Equipment/Method Training Log

See attached to Q Pulse record.

6. Appendix 2 – Verification of New Equipment Log

See attached to Q Pulse record.