Northern Ireland Blood Transfusion Service	POLICY DOCUMENT

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Document Title: EQUIPMENT AND MEDICAL DEVICE MANAGEMENT POLICY

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Written By: Angela Macauley, Quality & Regulatory Compliance Manager

Signature: _____ **Date:** _____

Authorised By: Karin Jackson, Chief Executive

Signature: _____ **Date:** _____

CROSS REFERENCES

This Policy refers to the following documents:

Doc Type	Doc. No.	Title
SOP	BE:085	REES Temperature Monitoring System
SOP	GL:004	Equipment Criticality
SOP	GL:006	Equipment Maintenance
SOP	GL:007	Equipment Log Preparation
SOP	GL:009	Purchasing/Leasing GxP Equipment, Purchasing Reagents, Consumables and Setting Up Maintenance Contracts.
SOP	GL:010	Disposal of GxP Equipment
SOP	GL:014	Use of Comark Data Loggers for Temperature Monitoring
SOP	HS:011	Health and Safety Risk Assessment Procedure
SOP	QA:070	Procedure for Reporting and Management of Quality Incidents
SOP	QA:081	Change Control Procedure
SOP	QA:100	Management Of Safety/ Hazard Notices Received At NIBTS
SOP	VL:001	Non-IS Validation Procedure
SOP	VL:028	Annual Equipment Revalidation/Requalification.
POL	HP:005	Use of Work Equipment Policy
POL	VP:003	NIBTS Temperature and Relative Humidity Mapping Policy

Key Change from Previous Revision:

This is a new policy.

1 STATEMENT

NIBTS utilises a variety of medical devices and equipment within the process of collection, processing, testing, storage and distribution of blood and in delivering patient testing services.

The use of equipment/medical devices and any associated reagents or consumables must meet the requirements of the relevant regulations (see section 4.7) and good practice guidance.

NIBTS aim to ensure that all equipment used for the purpose of collecting, processing, testing, storage and distribution of blood and/or delivery of patient testing is:

- Qualified, calibrated, and maintained to suit its intended purpose.
- Has operating instructions available.
- Has any hazards to donors, personnel and blood components identified and minimised and documented by performing a Health & Safety risk assessment.
- Is used in areas set up to assist the work flow and prevent mix ups. Areas should have enough space to safely operate equipment and allow staff to move around safely.
- Located and used in an area where environmental conditions are suitable for the equipment/medical device being utilised e.g. temperature/humidity.
- Only used with reagents and materials from approved suppliers which meet the documented requirements and specifications.

NIBTS will maintain an inventory of all equipment used for the purposes described above.

NIBTS will ensure regular Planned Preventative Maintenance (PPM) is performed and maintain records of PPM schedules and performance. Documented instructions for maintenance, servicing and cleaning will be available.

All GMP critical equipment will be subject to Annual Equipment Requalification and periodic review.

Staff will be trained in the use of medical devices and equipment relevant to their job role.

2 OVERVIEW

2.1 The Blood Safety and Quality Regulations and ISO 15189 - Requirements for quality and competence, require all equipment to be qualified, calibrated and maintained. All validated processes must use qualified equipment.

2.2 NIBTS recognises that equipment and medical device management is essential to ensure the production of blood components, which are safe and effective and in ensuring accurate tests results for patient testing.

2.3 Ongoing review of the status of equipment management will be via monthly Quality Improvement Review meetings attended by the Senior Management Team and Department Heads.

2.4 To ensure appropriate Clinical Governance any significant equipment validations and/or medical device alerts will be included in the quarterly governance and risk management report to be reviewed at the Governance and Risk Management meeting attended by Board Members and Senior Management.

2.5 Further oversight of equipment/medical device management is also achieved via the Medical Devices and Equipment Group which meets on a quarterly basis and is composed of representatives from Laboratories, Donor Services, Quality, IM&T and Facilities.

3 RESPONSIBILITY

3.1 Board, Chief Executive, Senior Management Team and Departmental/Section Heads.

4 POLICY

4.1 PURCHASE OF GXP EQUIPMENT/MEDICAL DEVICES/REAGENTS AND CONSUMABLES.

The NIBTS approach to purchase of equipment and/or medical devices and associated reagents/consumables is described in SOP:GL:009 'Purchasing/Leasing GxP Equipment, Purchasing Reagents, Consumables and Setting up Maintenance Contracts'.

Purchase must be from an approved supplier.

The purchase of cannibalised equipment for use in GxP activities is not permitted.

Where possible and operationally feasible, the purchasing process should be used to achieve standardisation of equipment to single models throughout the organisation.

Purchased equipment must be CE marked in line with the EU Regulations for in vitro diagnostic medical devices. Where it is not possible to purchase CE marked equipment/reagents for the test/process to be performed a health institution exemption (HIE) will be required post May 2022.

An equipment log will be developed for GxP equipment purchased as per SOP:GL:007 Equipment Log Preparation.

GxP Equipment will be assessed regarding the impact of equipment on donor and patient health and thereby assigned a GxP criticality status as per SOP:GL:004 'Equipment Criticality'.

4.2 PPM/FAULT REPAIR/CALIBRATION OF GXP EQUIPMENT/MEDICAL DEVICES

SOP:GL:006 'Equipment Log Maintenance' provides details regarding the NIBTS approach to equipment maintenance and calibration.

A PPM schedule must be agreed and documented for GxP equipment.

All equipment should be maintained +/- two weeks of the due date.
If PPM is carried out more than two weeks after a PPM date, a quality incident **must** be raised as per SOP:QA:070 'Procedure for Reporting and Management of Quality Incidents'.

The equipment should be taken out of service until the PPM is complete unless there is documented evidence from the service provider to verify that the equipment is still suitable for use during the extended period. If the equipment is critical to the continuation of service by the NIBTS the appropriate senior manager may, on consultation with the Quality and Regulatory Compliance Manager, authorise the continued use of the equipment as well as raising an incident. Appropriate records should be made on the incident record and should include explanation for the delay.

PPM service documentation provided by the contractor must be checked by an appropriate NIBTS member of staff to ensure the service has been completed as required, all measured values fall within the appropriate acceptable ranges and where PPM involves a calibration step the 'as found as left' values are stated and are acceptable.

Where appropriate post PPM checks must be completed prior to return of the equipment to routine use.

Calibration certificates must be obtained for any equipment used during PPM where relevant and calibration status confirmed as current.

Hard copy records of PPM checks will be retained in the Equipment Log and Q Pulse updated to reflect completion of PPM.

SOPs should be available describing the process for cleaning and maintenance of equipment.

4.3 QUALIFICATION OF GXP EQUIPMENT/MEDICAL DEVICES

All GxP Equipment must be qualified prior to being introduced into routine use. Qualification will include, where applicable, both hardware/software and any reagents/consumables to be used. The process for validation is described within SOP:VL:001 'Non-IS Validation Procedure'.

SOPS for use of the equipment should be drafted during validation including requirements for cleaning, maintenance and calibration. Users of the equipment must be trained in these procedures.

All validated processes must use qualified equipment.

During installation and qualification any health and safety risks should be identified, and where possible mitigated as per policy POL:HP:005 'Use of Work Equipment Policy' and SOP: HS:011 'Health and Safety Risk Assessment Procedure'.

All modifications, enhancements or additions to validated systems and equipment must be managed through the change control procedure SOP:QA:081 'Change Control Procedure 'and where required further qualification executed.

Annual requalification of equipment is required as per SOP: VL:028 'Annual Equipment Revalidation/Requalification'.

Where equipment is being used to store blood products or GxP critical reagents the equipment will be temperature mapped annually as per POL:VP:003 'NIBTS Temperature and Relative Humidity Mapping Policy'.

Continuous monitoring arrangements for temperature will be implemented for equipment used to store blood products or GxP critical reagents (See SOP: BE:085 'REES Temperature Monitoring System' and SOP:GL:014 'Use of Comark Data Loggers for Temperature Monitoring').

4.4 MEDICAL DEVICE ALERTS/FIELD SAFETY NOTICES

Medical Device Alerts will be reviewed, circulated and actioned as described in SOP:QA:100 'Management of Safety/ Hazard Notices Received at NIBTS'. Where an impact to NIBTS is identified this may be managed via change control as per SOP: QA:081 and/or the incident management process as per SOP:QA:070.

Where Field Safety Notices are received relevant to equipment/medical devices/reagents or consumables these will be reviewed by the relevant departmental manager and managed via change control as per SOP:QA:081 and/or the incident management process as per SOP:QA:070.

4.5 DISPOSAL OF GXP EQUIPMENT/MEDICAL DEVICES

Disposal of GxP Equipment/Medical Devices is described in SOP:GL:010 'Disposal of GxP Equipment'.

Disposal must be carried out in line with any environmental and regulatory requirements.

Where applicable arrangements should be made regarding the retrieval and archive of any stored data relevant to GxP processes prior to disposal.

Any personal data must be deleted prior to equipment/medical device being disposed.

A periodic review of the equipment must be executed prior to disposal to demonstrate the equipment was working as expected when last used.

4.6 MONITORING OF GXP EQUIPMENT/MEDICAL DEVICES

Fault logs should be maintained for all GxP Equipment/Medical Devices and reviewed regularly for trends by the equipment owner.

Results for controls/working standards, where available, should be monitored for trends by the equipment owner.

Completion of PPMs/overdue PPMs will be monitored monthly and data presented at the Quality Improvement Review Meeting.

Completion of Annual Equipment requalification's and/or periodic reviews will monitor and identify trends with faults/QC failures or other incidents which may indicate slippage in performance.

Qualification Status of Equipment will be reviewed at the Annual Quality Management Review Meeting.

Significant equipment validations and/or medical device alerts will be included in the quarterly governance and risk management report to be reviewed at the Governance and Risk Management meeting attended by Senior Management and Board Members.

4.7 REFERENCES

1. ISO15189:2012 Medical Laboratories – Requirements for quality and competence.
2. Blood Safety and Quality Regulations – 2005 (as amended).
3. Guidelines for Blood Transfusion Services in the United Kingdom.
4. Good Practice Guidelines for Blood Establishments Required to Comply with Directive 2005/662/EC.
5. Rules and Guidance for Pharmaceutical Manufacturers and Distributors.
6. Medical Device Regulation **-** Regulation (EU) 2017/746 of The European Parliament and of the Council.
7. In Vitro Medical Device Regulation - Regulation (EU) 2017/746 Of The European Parliament and of the Council.

5 EQUALITY SCREENING OUTCOME

This policy has been drawn up and reviewed in light of the statutory obligations contained within Section 75 of the Northern Ireland Act (1998). In line with the statutory duty of equality this policy has been screened against particular criteria. If at any stage of the life of the policy there are any issues within the policy which are perceived by any party as creating adverse impacts on any of the groups under Section 75 that party should bring these to the attention of the Head of HR & Corporate Services.

The Northern Ireland Blood Transfusion Service is committed to the promotion of equality of opportunity for staff, donors and service users. We strive to ensure that everyone is treated fairly and that their rights are respected at all times. We believe that it is important that our policy is understood by all those whose literacy is limited, those who do not speak English as a first language or those who face communication barriers because of a disability. On request it may be possible to make this policy available in alternative formats such as large print, Braille, audio file, audio cassette, Easy Read or in minority languages to meet the needs of those not fluent in English.

6 TRAINING REQUIREMENTS

Chief Executive, Senior Management Team and Departmental/Section Heads must read and understand this policy.