# Clinical Policy

**Please note that all sections below must be completed**

| | | | | | |
|---|---|---|---|---|---|
| **Document Name** | Medical Equipment Policy | | | | |
| **Document Summary** | To ensure safe effective lifecycle management of all medical equipment managed by Medical Physics | | | | |
| **Associated Documents** | Q-Pulse links used throughout | | | | |
| **Target Audience** | All staff who are involved in any aspect of the medical equipment lifecycle (selection, procurement, use, training, support and disposal) | | | | |
| **Medicine Related** | No | | | | |
| **Document Lead(s)** | Steven Friel | | **Document Author(s) (if different)** | | |
| **Date of this version** | 19/04/22 | **Date of next review** | Under Review | **Version number** | 4 |
| **Division** (Corporate, HLD, NES) | HLD (but applies to all) | | **Service** This is the service staff will expect to find this document on SharePoint i.e Cardiology, Ortho | All | |
| **Approving group / committee(s)** | Medical Device Committee | | **Record of Approval** | Not required – minor changes | |
| **Realistic Medicine** Have the pillars of Realistic Medicine been considered as part of the document development / review | Yes (not applicable) | | **EQIA** *Does the content / topic of your document require a completed EQIA* | No | |

| |
|---|
| **Have you made any changes as part of your review: No** |
| **If yes, please list any key changes made to this Policy as part of the review:** |

**NHS Golden Jubilee Values Statement**

What we do or deliver in our roles within the NHS Golden Jubilee is important, but the way we behave is equally important to our patients, customers, visitors and colleagues. We know this from feedback we get from patients and customers, for example in "thank you" letters and the complaints we receive.

Recognising this, the NHS Golden Jubilee have worked with a range of staff, patient representatives and managers to discuss and promote our shared values which help us all to deliver the highest quality care and service across the organisation. These values are closely linked to our responsibilities around Equality.


Our values are:

- Valuing dignity and respect.
- A 'can do' attitude.
- Leading commitment to quality.
- Understanding our responsibilities.
- Effectively working together.

Our policies are intended to support the delivery of these values which support employee experience.

# Contents

# Medical Equipment Policy

## 1.0 Introduction

Medical equipment is key to the delivery of healthcare services across the NHS Golden Jubilee Board. Effective management of these resources minimises risk, ensuring all equipment is:

- Suitable for its intended purpose
- Properly understood by the user
- Appropriately maintained
- Used only for its intended purpose
- Procured in a controlled, co-ordinated way demonstrating best value for the Board taking into account whole-life costs

Specific guidance published by the Medicines and Healthcare products Regulatory Agency (MHRA) and the Scottish Government are fundamental to the formation of this policy:

- MHRA Managing Medical Devices (2014)
- Scottish Government CEL 35 (2010) A policy for Property and Asset management in Scotland
- SHTN 00-04 (2021) Guidance on Management of Medical Devices and Equipment in Scotland's Health and Social Care Services

The Board carries out a range of equipment intensive clinical specialities, each requiring highly complex specialist medical devices. This policy outlines the organisation's systematic approach to complete medical equipment lifecycle management. It aims to ensure that safety standards and applicable legislation are adhered to at all times.

### 1.1 UK Legislation

The UK-EU Withdrawal Agreement (Brexit) has prevented the planned transition to the revised harmonised EU Medical Device Regulations (EU MDR). The updated EU regulation will NOT be passed into law in Great Britain. Instead, the UK Medical Devices Regulations 2002 (UK MDR) remain in place.

A brief summary of the impact of this change is included in Appendix 2.

## 2.0 Medical equipment definition

For the purposes of this policy, the terms medical device and medical equipment are inter-changeable. The UK Medical Devices Regulations 2002 (UK MDR) legally defines a medical device as follows:

"medical device" means an instrument, apparatus, appliance, material or other article, whether used alone or in combination, together with any software necessary for its proper application, which —

- is intended by the manufacturer to be used for human beings for the purpose of-
    - diagnosis, prevention, monitoring, treatment or alleviation of disease,
    - diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
    - investigation, replacement or modification of the anatomy or of a physiological process, or
    - control of conception; and

- does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, even if it is assisted in its function by such means, and includes devices intended to administer a medicinal product or which incorporate as an integral part a substance which, if used separately, would be a medicinal product and which is liable to act upon the body with action ancillary to that of the device;

## 2.1 Differentiating between re-usable and single use devices

Medical devices can be broadly split into two main categories:

1. re-usable
2. single use and limited usage devices

Table 1 provides examples of medical devices in each category and details the associated organisational roles and responsibilities.

| **Description** | **Re-usable medical devices/equipment** | **Single use and limited use medical devices** |
|---|---|---|
| **Examples** | Ventilators | Syringes |
| | Infusion Devices | Bandages |
| | Patient Monitoring | Gloves |
| | | Walking sticks |
| | | |
| **Responsible Group** | Medical Equipment Group | Clinical Users Group |
| **Management** | Medical Physics | Materials Management |

Table 1

The broad definitions above cover the vast majority of medical devices. However, there are a small range of devices where organisational management responsibility lies with heads of department or specialist service provider groups.

| | |
|---|---|
| **Estates/Department Heads** | Theatre tables |
| | Beds |
| | Wheelchairs |
| | Transportation trolleys |
| | Patient hoists |
| | Pendants and booms |
| **Heads of Department** | Pressure mattresses |
| **Rehabilitation** | Walking aids |

Table 2

Organisational responsibility for managing medical equipment safety (Hazard) alerts and ensuring the appropriate external reporting of equipment related incidents lies with the Equipment Coordinator, regardless of category, ownership or management.

Unless otherwise stated, all references to Medical equipment in this policy relate to the re-usable items managed by Medical Physics as detailed in table 1. Items of equipment managed by other departments or specialist service provider groups are managed under separate systems of work.

# 3.0 Responsibilities

## 3.1 Chief Executive

The Chief Executive has overall accountability for ensuring the Board has effective systems and controls in place to meet regulatory standards for the management of medical equipment. This includes ensuring that procedures exist to manage risks relating to medical equipment, the reporting of adverse events and the dissemination of safety (Hazard) notifications.

### 3.2 Medical Director

Executive responsibility for medical equipment management lies with the Medical Director. Responsibilities include:

- Ensuring efficient and effective medical equipment procurement planning is in place
- Ensuring operational lifecycle management of medical equipment is appropriately monitored and controlled
- Executive Sponsor of the Medical Equipment Group

Responsibilities for re-usable medical equipment are included within appropriate schemes of delegation to the Head of Medical Physics with ongoing assurance, monitoring and validation of equipment planning and strategy being performed by the Medical Equipment Group. Assurances regarding these arrangements are provided within the Property and Asset Management Strategy and Medical Equipment Management Strategy.

### 3.3 Head of Medical Physics

The Head of Medical Physics is the operational and strategic lead for medical equipment lifecycle management. Responsibilities include:

- Production of medical equipment strategy
- Production of medical equipment management operational policies procedures and systems of work
- Production of long term, medium term and short-term equipment procurement plans
- Continual quality improvement of all aspects of medical equipment lifecycle management
- Chair and administrate the Medical Equipment Group
- Provide medical equipment expert advice to organisational committees
- Contract management
- Linking with national groups relating to Medical Equipment Lifecycle Management

### 3.4 Director of Nursing, Associate Medical Directors and Directors of Operations

The Director of Nursing, Associate Medical Directors and Directors of Operations are accountable to the Medical Director for ensuring that this policy is implemented within their respective Service Units and Directorates. In addition, Directors of Operations will:

- Verify all equipment plans to ensure compatibility with ongoing strategies
- Verify all equipment purchases within their respective directorates ensuring that that all lifecycle running costs (consumables, maintenance) are identified and appropriately aligned to budgets

### 3.5 Equipment Coordinator

The role of Equipment Coordinator as laid out in CEL 43 (2009) is formally held by the Head of Medical Physics. The Equipment Coordinator supports the designated Executive Director (Medical Director) in achieving the aims of the CEL.

The Equipment Coordinator acts as a single point of contact between the Board, Health Facilities Scotland and the MHRA for all safety issues relating to medical equipment and is responsible for:

- Ensuring managers and staff are aware of the procedures for reporting equipment related adverse incidents for implementing safety advice
- Monitoring all equipment related adverse incidents reports from within the Board
- Receiving emails from Health Facilities Scotland (HFS) and the MHRA notifying of alerts and bulletin, and cascading within own organisation
- Monitoring relevant websites for information on equipment safety and management issues
- Discussing equipment safety issues with HFS and the MHRA
- Promoting equipment safety by staff education and training
- Building and maintaining communication links with HFS
- Attending Equipment Coordinators conferences and seminars
- Monitoring internal cascade systems to ensure alerts are received, assessed and acted on

The role of the Equipment Coordinator is broadly comparable with the role of the MHRA Medical Devices Safety Officer in NHS England.

### 3.6 Head of Procurement

The Head of Procurement is responsible for:

- Achieving and demonstrating value for money though purchasing arrangements
- The prevention of rogue medical equipment purchases
- Oversight and expert adviser role in all equipment procurement
- Ensuring appropriate policies, systems and controls are in place to ensure all medical equipment procurement is carried out in accordance with the Board's Standing Financial Instructions and all applicable regulation and legislation

### 3.7 Heads of Department / Service

Heads of Department / Service have a managerial responsibility to ensure that medical equipment is used in a safe manner. This includes:

- Having appropriate processes in place to ensure manufacturers instructions are adhered to
- Identifying and addressing training needs
- Ensuring operators are adequately trained, competent and confident to use the equipment
- Identifying, assessing and addressing risks associated with medical equipment within their departments and operational areas of responsibility
- Ensuring the equipment is looked after in day-to-day use
- Ensuring Hazard notices are responded to promptly

Heads of department also play an important role in identifying equipment requirements and advising the procurement process as a senior user.

### 3.8 All staff

The Board requires that all staff are competent and trained in the confident use of any medical equipment that they are required to use. All equipment users must ensure that medical equipment is only used as instructed by the manufacturer, for its intended purpose. Equipment users have primary responsibility for treating the equipment in a careful manner that is consistent with its importance and cost. Responsibilities also include pre-use checks and routine user maintenance and decontamination where required.

## 3.9 Committee responsibilities

### 3.9.1 The Medical Equipment Group

The Medical Equipment Group (MEG) is the key medical equipment governance group. It has as multidisciplinary membership comprising of clinical leads from all specialities and heads of department from all user areas. The MEG has the following key functions:

- Enables robust clinical input to medical equipment planning and acquisitions, allowing appropriately governed prioritisation and approval of purchases in the context of ongoing clinical strategies
- Allows Executive Director to delegate responsibility to Head of Medical Physics in an appropriate, controlled and monitored manner
- Allows Executive director and other stakeholders to monitor equipment lifecycle management performance against Key Performance Indicators and continuously evaluate the implementation of policy.

### 3.9.2 The Clinical Users Group

The Clinical User Group (CUG) is established to safely manage change relating to the use of all consumable medical devices. Responsibilities include:

- Coordination of the trial, review and evaluation of all new or alternative consumable medical devices used within NWTC Board
- Acts as a interface between the Board and Regional West of Scotland Technical User Groups as well as National Commodity Advisory Panels

The CUG is a multidisciplinary group with representation from key clinical areas and specialities. The group is chaired by the Associate Medical Director.

### 3.9.3 Capital Group

The Capital Group oversees and authorises the procurement of all re-usable medical devices. This includes revenue items. All device purchases are initially approved and prioritised by the MEG. The function of the Capital group in this context is:

- To approve funding for medical equipment purchase in line with equipment plans and other ongoing capital plans
- To ensure all lifecycle running costs (consumables, maintenance) are identified and appropriately aligned to budgets
- To ensure all medical equipment purchases receive formal approval from Head of Operations, Medical Physics, Infection Control, Procurement, IM&T, Housekeeping and CSPD.

## 3.10 Specialist equipment groups

The Board has a number of specialist equipment groups established to oversee equipment usage where specific risks exist. The groups are multidisciplinary and comprise of stakeholders appropriate to the specific equipment speciality. The main remits of the groups include:

- To safely manage change
- To ensure that appropriate advice, recommendations and legislation is adhered to

These groups include:

1. Infusion Device Committee
2. Point of Care Testing Committee
3. Ionising Radiation Safety Committee

## 4.0 Medical equipment lifecycle management

Medical equipment lifecycle management of re-usable medical equipment can be effectively summarised in the following diagram.

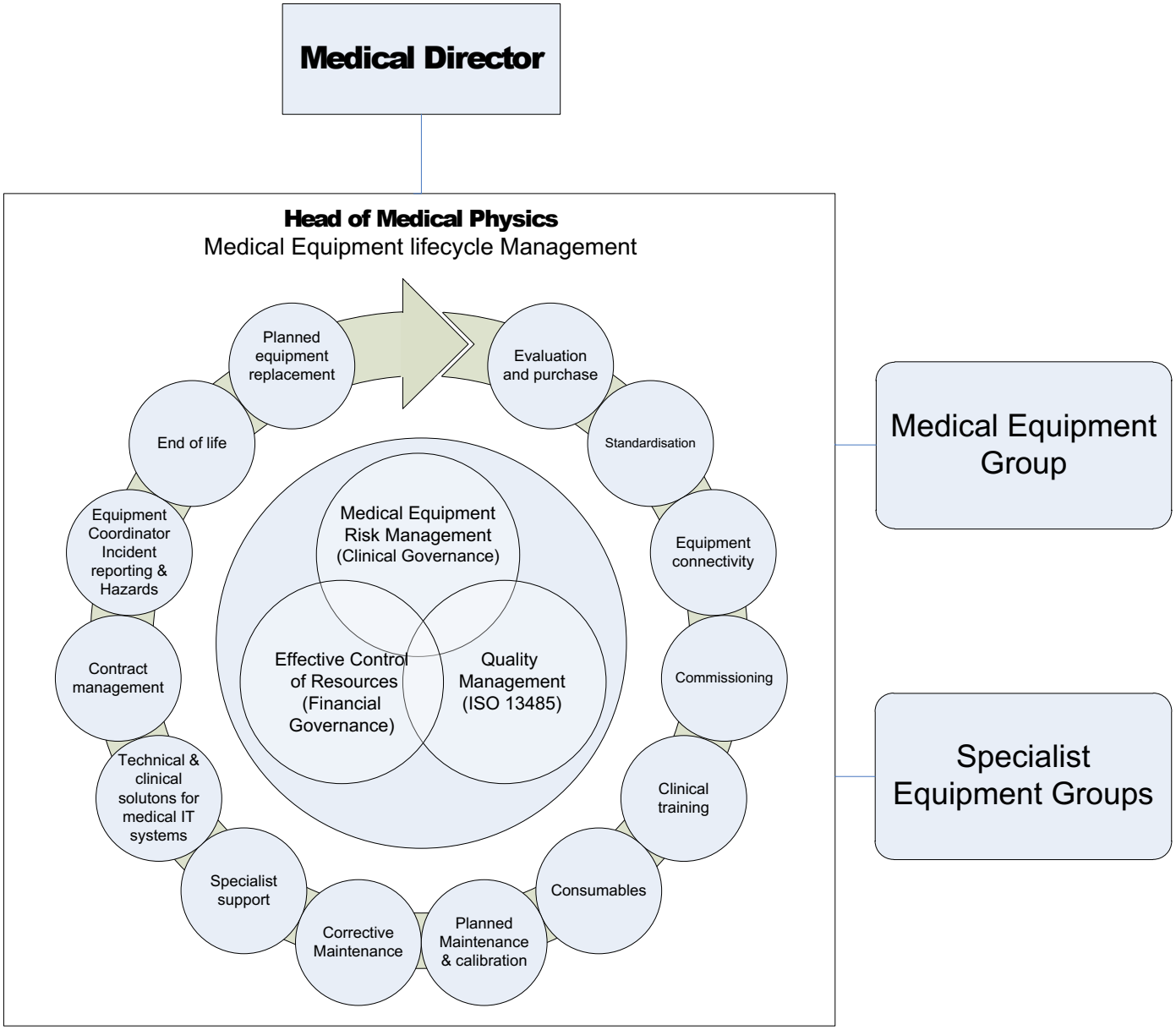


Figure 1: Medical Equipment Lifecycle Management

### 4.1 Selection and procurement

The process for the selection and procurement of reusable medical equipment is defined in the Board's policy.

CS-MPH-POL-10, Medical Equipment Funding and Acquisition Policy

The process is overseen by Materials Management with appropriate expert advice and direction provided on an ongoing basis. It is designed to eliminate rogue purchases and ensure appropriate stakeholder involvement. The process ensures Infection Control input to all medical Equipment purchases. Tenders for high value procurements include assessment of environmental and sustainability credentials of equipment suppliers and the medical equipment under consideration.

### 4.1.1 Standardisation and connectivity

The procurement process ensures that consideration is given to equipment standardisation and connectivity. The main driving force for equipment standardisation is the management of risks associated with equipment usage (training, familiarity, reducing variation). It also minimises maintenance and consumable costs, reducing overall lifecycle spend. Standardisation also enables a high level of connectivity and integration between devices to be effectively implemented.

## 4.2 Commissioning

It is essential that all new equipment is checked against specification and receives safety checks before being placed into clinical use. A dedicated acceptance check procedure exists to define and standardise the commissioning process.

CS-MPH-PRO-12, Acceptance Check Procedure

The procedure describes:

- Delivery checks
- Pre-use checks
- Electrical Safety checks
- Storage during commissioning
- Record keeping
- Documentation management

### 4.2.1 Electronic inventory

The commissioning process requires important equipment management information relating to medical equipment to be stored on an electronic inventory. Good record keeping underpins the safe and effective management of medical devices. The Medical Physics Database is a centralised equipment management database designed to allow the Board to appropriately administer its medical devices. The database meets all the requirements and minimum datasets set out in guidance by the MHRA and the Scottish Government. Functions of the database include:

- Electronic inventory
- Planned preventative maintenance management
- Corrective maintenance management
- Customer request management
- Contract management
- Planned equipment replacement
- Engineer dashboards
- Supplier administration
- KPI and customer metric generation
- Finance – asset register verification

A second parallel inventory of capital medical equipment exists in the Finance Asset Register.

### 4.2.2 Documentation (Instructions for use)

Good clear instructions for use have a crucial role in the continued safe and effective use of medical equipment. The lack of adequate instructions for use is recognised by the MHRA as a key equipment safety consideration and a root cause of adverse events.

When a new equipment type is first introduced to a department, a copy of the instructions for use is provided by Medical Physics. In addition to this, a central library of all instructions for use documents is held and maintained by the Medical Physics department. All users have access to the documents on request. Additional copies can also be made available. The process for the distribution of instructions for use is included in the Medical Physics acceptance check procedure.

## 4.3 Training

### 4.3.1 Clinical user training

All healthcare professionals working with medical equipment have a professional duty to ensure their own skills and training remain up to date. Training is a key element in device safety. The quality of training in the appropriate use of medical devices is a recognised root cause in the occurrence adverse incidents. All professional groups within the Board with a responsibility for the safe use of medical devices must have their own medical equipment training policies. The policies must define the requirement and process for adequate record keeping.

### 4.3.2 Technical training

Members of the Medical Physics department directly responsible for the repair and maintenance of medical equipment must be trained, qualified and have the necessary levels of competency to meet the operational requirements of the department. A dedicated training procedure exists to ensure that this requirement is met at all times.

CS-MPH-PRO-10, Training Procedure (Medical Physics)

The procedure describes the process for:

- Competency assessment
- Identifying training needs
    - Departmental requirements to meet service delivery
    - New members of staff
    - New equipment
- Producing a training plan
- Recording training on individual and departmental training matrixes

## 4.4 Maintenance and repair

Medical device maintenance and repair falls into two distinct categories, corrective maintenance and planned preventative maintenance. Corrective maintenance occurs when a device fails unexpectedly. The process for dealing with these failures ensures a swift response and resolution to any problems.

CS-MPH-PRO-4, Corrective Maintenance Procedure

Planned Preventative Maintenance (PPM) is managed routine maintenance, scheduled to take place at defined intervals and intended to prevent failures from occurring in the first place.

CS-MPH-PRO-8, PPM of Electromedical Equipment Procedure

### 4.4.1 Decontamination of medical equipment

Decontamination of medical equipment is covered thoroughly by the Board's infection control policies. All staff have a responsibility to ensure equipment is decontaminated before it is received by Medical Physics. All requests for corrective maintenance should be accompanied by a combined request/decontamination form.

Specific guidance for Medical Physics staff is included in the departmental policy.

CS-MPH-PRO-17, Infection Control Procedure (Medical Physics)

#### 4.4.2 Tracking

All maintenance operations are tracked by the call log system within the Medical Physics Database. All equipment undergoing repair is accompanied by a status label to indicate the equipment fault.

#### 4.4.3 Storage (control of product)

Robust control of product is essential to the safe application of the maintenance process. It is common for equipment to be in varying states of repair when stored in Medical Physics labs. It is essential that entry to the labs is controlled to ensure equipment is not disturbed or returned to use before repair is complete.

#### 4.4.4 Specialist support

The Medical Physics Department operates a single department structure across multiple clinical/technical specialities. This differs from the common model of operating multiple specialist departments (anaesthesia, cardiology, renal etc). The range of equipment covered is supported by Specialist Engineers in key specialities. These lead Engineers require more in-depth training and knowledge to address the specific requirements of this equipment and its clinical application.

### 4.5 Device manufacture and modification by Medical Physics

The in-house manufacture of medical devices is not included within the Medical Physics quality management system. Device manufacture will only be considered in exceptional circumstances when an equivalent device is not commercially available.

The MHRA Provides specific guidance on custom made devices in

http://www.mhra.gov.uk/Howweregulate/Devices/Complyingwithlegislation/ActiveImplantableMedicalDevicesDirective/Custommadedevices/index.htm

In house manufactured devices are exempt from CE Marking as long as they are only used within the manufacturing organisation. However, a robust formal risk assessment will be required to ensure:

- Electrical safety
- The device is cleanable
- Appropriate consideration is given to what happens if it fails
- Appropriate ‘conditions of use’ documentation is produced
- Controls are in place to ensure the equipment is only used within Board premises

### 4.6 Planned equipment replacement

The information held on the Medical Physics database is used to drive the planned equipment replacement programme. The programme generates a 10-year outline financial projection which is used to inform medium to long term capital planning.

One of the core remits of the Medical Equipment Group (MEG) is to oversee all medical equipment purchases in the context of clinical strategies. The group has strong clinical representation across all directorates and clinical specialities. Annual replacement lists derived from the planned equipment replacement plan are verified by the group before going on to form part of the Board’s annual capital plan.

The replacement programme also allows additional individual factors to be considered outwith the planned element of replacement. These are laid out in the 'medical equipment purchase process' and include whether the item is:

- Worn out beyond economic repair
- Damaged beyond economic repair
- Unreliable (based on service history)
- Clinically or technically obsolete
- Spare parts are no longer available
- Superseded by a more cost effective or clinically effective device
- Unable to be cleaned or decontaminated effectively

## 4.7 End of life (decommissioning and disposal)

A process for the removal from service and disposal of medical equipment is essential element of medical equipment lifecycle management. Equipment is regularly removed from use for a verity of reasons including:

- Equipment replaced as part of the planned equipment replacement programme
- Damaged or worn out beyond economic repair
- Clinical or technical obsolescence
- Disposal due to contamination, e.g. Creutzfeldt-Jakob (CJD) etc.
- Changes in local policies for device use
- Absence of manufacturer/supplier support
- Non-availability of correct replacement parts
- Non-availability of specialist repair knowledge

A dedicated procedure exists for the decommissioning and disposal of medical equipment.

CS-MPH-PRO-3, RTM Procedure

The procedure ensures compliance with the WEEE directive. A separate procedure is in place for the disposal of media containing sensitive data.

CS-MPH-PRO-35, Disposal of Media Containing Sensitive Data

## 4.8 Governance

### 4.8.1. Hazard notifications

For the purposes of this policy, the terms Hazard Notification. Safety Notice and Medical Device Alert are interchangeable.

Hazard notifications can originate from the MHRA, HFS, equipment suppliers, equipment manufacturers or can be internally generated by Medical Physics. Distribution and tracking of hazard notifications is the responsibility of the Equipment Co-ordinator (Head of Medical Physics). The process for handling hazard notifications is defined in the following policy.

CS-MPH-POL-5, Hazard and Safety Action Notice Policy

### 4.8.2 Medical equipment incidents

All incidents or near misses relating to medical equipment must be processed in line with the Board's standard incident reporting policy.

COR-CG-RM-POL-5, Incident Reporting Policy and Procedure

Incidents involving medical equipment must also be reported to Medical Physics immediately to ensure prompt investigation. Where possible, all material evidence relating to adverse events must be preserved, labelled and kept secure. This includes the medical device, consumables, packaging and any other means of batch identification. Equipment involved in serious incidents must not be tampered with and if necessary will be quarantined by Medical Physics. Incidents requiring external reporting to HFS or the MHRA will be managed in line with the Hazard and Safety Action Notice Policy. All external reporting must be channelled via the Equipment Coordinator (Head of Medical Physics).

CS-MPH-POL-5, Hazard and Safety Action Notice Policy

### 4.9 Evaluations

Equipment evaluation is a standard part of selection and procurement, and is encompassed by the Board's policy.

CS-MPH-POL-10, Medical Equipment Funding and Acquisition Policy

The policy ensures equipment is safe, indemnified and meets regulatory standards (is CE Marked).

### 4.10 Clinical research

The process for controlling equipment required for clinical research is managed by the Research and Development Department

### 4.11 Non CE marked devices

All medical devices placed on the market in the UK and European Union must bear the CE Marking to demonstrate they meet the essential requirements of the Medical Device Directive. This helps ensure that they do not compromise the safety and health of patients, users and other persons when properly installed, maintained and used in accordance with their intended purpose.

The use of non CE marked devices is strictly prohibited within the NWTC Board unless carried out under a formal research programme, managed by Research and Development. It is a legal requirement that the UK competent authority (the MHRA) is informed of any clinical investigation involving a non-CE-marked medical device within the UK. These requirements are managed by the Research and Development Department and include:

- MHRA Notification and confirmation letter of no objection
- Clinical Investigation Plan
- Research Ethics Committee approval
- Adequate training for equipment users
- Systems for control and segregation of non CE marked equipment limiting usage to named clinical investigators
- Signed informed patient consent
- Criteria for stopping or curtailing use

Under all other circumstances, non CE marked medical equipment must not be used.

## 4.12 Off label usage of medical equipment and user modifications

Use of a medical device for anything other than its intended purpose is referred to as ‘off label’.

- Medical Devices within the NWTC Board must NOT be used off label.
- Medical Devices within the NWTC Board must NOT be modified by users

The Medical Devices Regulations stipulate that the manufacturer of a device is responsible for establishing that the device is safe and that it is suitable for its intended purpose. To establish this, manufacturers implement appropriate controls on the device design and manufacture and evaluate the safety and performance of the device in its intended application. This involves an analysis of risks that could arise during use, an assessment of relevant pre-clinical and clinical data, the preparation of appropriate instructions for use and, if necessary, specific training schemes. From such activities, manufacturers are able to verify that risks have been eliminated or minimised and are judged acceptable when weighed against the anticipated benefits to patients.

Specific guidance on the off label use and user modification of CE marked medical devices is provided by the MHRA in MDA/2010/001.

http://www.mhra.gov.uk/home/groups/dts-bs/documents/medicaldevicealert/con068160.pdf

Important points include:

- The use of a device in these circumstances exposes users and patients to unknown and therefore unacceptable risks and may have legal and ethical implications

- As well as the risks to the patient and user, liability for the performance and safety of products that have been modified, adapted or used off-label, could be transferred to the user

- Ensure that you are familiar with the instructions for use including the intended purposes for all the devices you use

- Only use devices for their intended purpose; do not modify or alter the function or structure of medical devices unless specifically sanctioned by the instructions for use

- Where a healthcare professional judges there is no alternative to off-label device use, the patient must be fully informed during the consent procedure and a note made in the patient's records

**Exceptional circumstances**

Under exceptional circumstances it is conceivable that users may be presented with a situation where no commercially available medical devices are available that are CE marked for the required application. Under these circumstances a formally documented detailed risk assessment will be required. This will include input from Medical Physics, Materials Management, the equipment manufacturer and have signoff by the Medical Director. Documented patient consent will be required along with a note in the patient’s record.

## 4.13 Prescribing medical equipment

Any professional user who prescribes medical equipment for use by a patient must be qualified to do so. Non-qualified staff who issue equipment must have the necessary written authority from a professional user before releasing the equipment or have been deemed competent to release it themselves.

Managers must ensure that medical equipment is not issued to patients or carers without the issue of the appropriate instructions and training and having ensured that facilities for maintenance and repair have been clarified.

### 4.14 Accreditation

All medical equipment lifecycle management functions carried out by the Medical Physics department are performed to the ISO 13485 Quality Management Standard. This is certified by an independent body on behalf of UKAS, the sole national accreditation body recognised by government to assess against internationally agreed standards.

ISO 13485, Medical devices – Quality management systems – Requirements for regulatory purposes, is an internationally agreed standard that sets out the requirements for a quality management system specific to the medical devices industry. The standard represents an international consensus on good quality management practices. The application of the ISO 13485 standard in itself ensures that all internal processes minimise risk.

Compliance with a formal quality management system is a recommendation of the MHRA in Managing Medical Devices 2021 and is required in NHS Scotland as detailed in both CEL35 and SHTN-00-04.

#### 4.14.1 Audit and monitoring

Monitoring the organisation's medical device management performance is essential to minimise or eliminate risks to patients and staff. Patient safety is enhanced by the use of systemic activities that prevent or reduce the risk of harm to patients. The Board assesses the efficacy of these arrangements through the following mechanisms:

- Annual Internal audit of all equipment management processes
- Annual independent audit of the quality management system to the ISO 13485 standard
- Feedback from other auditing activities (example: NHS QIS, Anaesthesia – Care Before, During and after Anaesthesia)
- Review of medical device incidents

### 4.15 Outsourcing

All aspects of the medical equipment lifecycle management process are managed by the Board. No processes are directly outsourced. Service contracts exist for some medical equipment and co-operative agreements with suppliers are sometimes utilised.  In all instances management of the equipment is coordinated directly by Medical Physics.

## 5.0 Equipment financing

Arrangements concerning equipment financing are included within the Board's strategic finance plan and Property and Asset Management Strategy (PAMS).

## Appendix 1 Acronyms

| | |
|---|---|
| CE Marking | Conformité Européenne or European Conformity |
| CEL | Chief Executive Letter |
| CSPD | Central Sterile Processing Department |
| CUG | Clinical Users' Group |
| EEC | European Economic Community |
| HFS | Health Facilities Scotland |
| IM&T | Information Management and Technology |
| ISO | International Organisation for Standardisation |
| KPI | Key Performance Indicator |
| MEG | Medical Equipment Group |
| MHRA | Medicines and Healthcare products Regulatory Agency |
| PAMS | Property and Asset Management Strategy |
| QIS | Quality Improvement Scotland |
| WEEE | Waste Electrical and Electronic Equipment |

## Appendix 2 Medical device legal framework with respect to Brexit

**Medical Device Regulation**

- The updated EU Medical Devices Regulation (EU-MDR) will NOT be passed into law in Great Britain
- Instead, the Medical Device Regulation (UK -MDR) 2002 remains in place.
- The exception within the UK is Northern Ireland. Northern Ireland has 'special status' and EU Rules will continue to apply.
- So: Manufacturers intending to sell equipment in Great Britain need to comply with the older 2002 regulation.

**CE marking**

- The UK will continue to recognise the EU CE mark until June 2023
- From July 2023 all medical devices must be provided with a UK Conformity Assessment (UKCA mark)
- The EU will not recognise the UKCA mark.
- Manufacturers will have to apply to conform with both
- In addition to UKCA marking, non-UK based manufacturers will need to appoint a UK Responsible Person as the MHRA will only accept applications from UK based companies or UK based responsible Persons.

**UDI – Unique Device Identification**

- Currently no mandated requirement.
- Is mentioned in US regulations
- Currently under development in EU

**In-House Manufacturing**

- Medical Device Directive 2002 applies
- Healthcare exception remains in place allowing local manufacture for use by the same legal entity.
- Current UK guidance only recommends that a formal Quality Management System (QMS) should be in pace. This is expected to tighten in coming years. Good governance would suggest that a formal QMS incorporating the same controls expected from a commercial device manufacturer should be utilised.
- Specific NHS Scotland guidance is included in SHTN-00-04, stating that Manufacturers of custom-made devices shall have a formal QMS in place