University Hospitals of Leicester NHS
NHS Trust

Medical Devices Policy

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Trust Lead:	Jasdip Mangat – Head of Clinical Engineering
Board Director Lead:	Medical Director
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CONTENTS

REVIEW DATES AND DETAILS OF CHANGES MADE DURING THE REVIEW

Changes made during Review March 2025

- Replace all reference to AIMs database to eQuip.
- Remove reference to medical device standardisation group.
- Remove reference to standard equipment list.
- Replace reference to CEDAR to eFinancials
- Update flowchart 1 and flowchart 4 as per above.
- Added EDI statement to section 8
- Updated references from MEMS to CE
- Updated references from Insite to UHL Connect
- Added UKCA reference to Appendix 10

KEY WORDS

Medical Devices

Medical Equipment

Accessory

Consumable

Training

Planned Preventative Maintenance (PPM)

Incident

Capital

1 INTRODUCTION AND OVERVIEW

1.1 This document sets out the policy for the management of Medical Devices within the University Hospitals of Leicester NHS Trust (UHL) including procurement, acceptance, risk assessment, incident reporting, maintenance, decontamination and disposal. The detailed procedures for this are set out in the appendices accompanying this policy.

1.2 Medical devices are used widely in UHL for diagnosis, monitoring and treatment. The aim of this policy is to ensure that Medical Devices are subject to well governed processes that ensure benefits to patients from the use of Medical Devices are maximised, risks minimised, and medical equipment and its management represents value for money.

1.3 This policy contains statements relating to the requirements of the Care Quality Commission (CQC). The policy also relates to guidance from the Medicines and Healthcare products Regulatory Agency (MHRA).

2 POLICY SCOPE – WHO THE POLICY APPLIES TO AND ANY SPECIFIC EXCLUSIONS

2.1 This policy applies to all staff employed by UHL (including those on bank, agency or honorary contracts), staff from external maintenance agencies and from managed service contract providers.

2.2 This policy applies to the following Medical Devices:

a) Those listed in section 3.6 of this policy and purchased by the Trust from Exchequer and Charitable Funds and intended to be re-usable and those loaned or donated to the Trust and intended to be re-usable.

b) Those that are re-usable and owned by the University of Leicester and used on or near patients

c) Those owned by UHL but managed on their behalf by a third-party service provider, such as the surgical instruments management contract

d) Those provided under lease / contract, such as the managed equipment service contract for imaging equipment and the bed and equipment management contract

e) Those provided as part of a lease / contract for medical consumables (the device usually being provided free of charge)

f) Those intended to be single use and single patient use

g) Point of Care Testing (POCT) devices; this range of devices will comply with this overarching policy, but also has its own policy; Management of Point of Care Testing (POCT) Devices Policy (B16/2013).

h) Medical Device accessories.

2.3 This policy does not apply to all laboratory equipment including analysers used for diagnostic purposes or non- medical equipment e.g., kettles, toasters, and microwaves.

2.4 Systems for controlling radiation risks arising from the use of Medical Devices which emit Ionising or Non-Ionising radiation are described in the UHL Ionising Radiation (Medical Exposures) Regulations 2017 B13/2001 and the UHL Non-Ionising Radiation Safety Policy B25/2019.

3 DEFINITIONS AND ABBREVIATIONS

3.1 '**Accessory** for a Medical Device' means an article which, whilst not being itself a Medical Device, is intended by its manufacturer to be used together with one or several particular Medical Device(s) to specifically enable the Medical Device(s) to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the Medical Device(s) in terms of its/their intended purpose(s).

3.2 **Consumable** is a product used with a device or a device accessory that are regularly consumed, although not necessarily disposed after single use (see 3.8 below), although single use devices are also within the consumable category of devices. An example of a consumable device are things like Oxygen cells for anaesthetic machines or ventilators, or a disposable blood pressure cuff.

3.3 Where used in this document the terms **Equipment Owner and Budget Holder** are synonymous with each other.

3.4 An **Implantable Medical Device** is any Medical Device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure.

3.5 A **Medical Device** is defined under EU directive 93/42/EEC as: " any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability
- investigation, replacement or modification of the anatomy or of a physiological or

pathological process or state
- providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

The following products shall also be deemed to be Medical Devices:
- devices for the control or support of conception.
- products specifically intended for the cleaning, disinfection or sterilisation of devices.

3.6 The term **Medical Devices** comprise of a wide range of equipment types. At UHL these will be considered as the following groups:

- *Medical Equipment (Non-powered & Electrical)
- Consumables & Single use
- Surgical Instruments
- *Laboratory & Point of Care Testing (POCT)
- *Rehabilitation & Patient Support
- Implantable Medical Devices (Active & Non-active)
- *Imaging & X-Ray

3.7 **Medical Equipment** is the term used to describe the subgroup of Medical Devices that includes electro-mechanical medical equipment. (those with an (*) Asterix in section 3.6.

3.8 **Single-use Device** is the term used to describe any Medical Device intended to be used on an individual patient during a single procedure and then discarded. Items labelled or recommended by the manufacturer as single use must not be reprocessed and used on another patient.

3.9 **Super-users** is a term used for trust employed staff who are experts in the use of specific Medical Devices and can offer additional training and support to other employees one-on-one or in small groups.

3.10 **Whole Life Costs** is the term used to describe all the costs associated with owning a piece of medical equipment, e.g. maintenance, consumables, training, as well as initial procurement of the actual device.

3.11 Abbreviations

CE – Clinical Engineering

POCT- Point of Care Testing

PPM – Planned Preventative Maintenance

4 ROLES – WHO DOES WHAT

4.1 Executive Team

a) The **Medical Director** is responsible at Board-level for the management of Medical Devices throughout the Trust. The Medical Director acts in the role of Executive Lead for the Medical Equipment Executive (MEE) Committee.

b) The Executive Quality Board (as **Executive Team)** will take responsibility only for those Medical Devices which have been accepted as described in this policy

c) Where required the Executive Team will appoint nominated members of staff to act in the role of **Lead Officer** for the CQC standards relating to medical equipment and devices. The appointees will advise the Trust in regard to overall compliance with the standard.

4.2 **UHL Medical Equipment Executive Committee (MEE)** will be:

a) Responsible for providing assurance to the Trust that CQC Standards and MHRA guidelines relating to Medical Devices are being achieved. The MEE is chaired by a senior clinician, with delegated authority from the Medical Director. The reporting structure for Medical Devices through MEE to the board is shown in Appendix 11.

b) An advisory sub-group of the Trust Executive Quality Board, Capital Monitoring and Investment Committee for matters relating to Medical Equipment.

c) Responsible for establishing maintaining and monitoring UHL strategy, policy and procedures relating to any aspects of Medical Devices management applicable to the Trust including:

- Capital and revenue Planning
- Procurement/Finance
- Regulatory Compliance (including CQC Fundamental Standards)
- Risk Management (including incident reporting)
- Standardisation of equipment
- Decontamination of Medical Equipment
- Managed Equipment Service
- Monitoring of inventory
- Audits
- Disposal
- Learning and sharing best practice from Serious Untoward Incidents
- Medical device training

e) All issues relating to equipment which produces Ionising or non-Ionising radiation will be referred to the Radiation Protection Committee structure.

4.3 **UHL Point of Care Testing (POCT) Committee** is responsible for:

a) Establishing POCT strategy.

b) Advising upon POCT policy and procedures for the Trust.

c) The development, Optimisation, assurance, safety, risk and quality management of POCT services and best practices - including point-of-care

Medical Device planning, acquisition, management, application and associated competency-based training.

This Group reports / is accountable to MEE.

4.4 **UHL Pillars of decontamination are responsible for:**

a) Advising upon Trust policy and procedures for the reprocessing of invasive Medical Devices

b) Assurance review and reporting upon Trust compliance in its decontamination practices.

c) Oversight of safety, risk and quality management relating to the management of contaminated invasive Medical Devices.

d) Contract management of the trust MES for sterile services.

e) Advise on new products compliance with trust decontamination policy

This Group reports / is accountable to the Infection Prevention Committee, but is also represented at MEE.

4.5 **UHL Medical Device Safety Group (MDSG)** is responsible for:

a) monitoring reporting of and analysing of incident data, audit and other data to identify, prioritise and address Medical Devices risks minimising harm to patients.

b) identifying, developing and promoting best practice for Medical Devices safety.

c) providing regular liaison to clinical areas and staff, and hospital committees on (internal and external) risks of Medical Devices and planned action to minimise these risks.

d) coordinating education and training support to improve the quality of Medical Devices error incident reports and safe Medical Devices practices.

This Group reports to MEE.

4.6 **UHL Medical Device Training Team (MDTT)** is responsible for:

a) coordinating education and training support to improve the quality of Medical Devices error incident reports and safe Medical Devices practices

b) Taking a lead role in the development and maintenance of a Medical Device training record system.

c) Creating and delivering Medical Device user training packages to staff.

d) Encourage and support Super Users to maintain their continued participation in Medical Device training.

e) Answer and act upon requests for Medical Device support and training from relevant staff.

f) Play a role in Medical Device selection exercises in terms of evaluating training packages and resources offered.

g) Play a part in the delivery and implementation of new medical equipment being delivered to the trust, ensuring training is provided and attendance maximised.

h) Communicate with Medical Device manufacturers to offer Medical Device refresher training sessions for staff as required.

i) Audit staff user training compliance and produce reports for monitoring.

4.7 **Clinical Management Group (CMG) Head of Ops/Deputy Head of Ops** are responsible for ensuring that the requirements of this policy are met and that staff within their teams comply with the requirements of this policy at all times. CMG teams are responsible for:

a) Ensuring equipment is procured in accordance with the Trust's purchasing policy and procedures and is selected with due regard for clinical suitability, quality and safety, and "whole life" costs and approved by the Medical Device standardisation group/POCT committee.

b) Ensuring new, loaned or donated medical equipment comply with the Policy for the Donation and Loan of Equipment, UHL Policy (B19/2004) and are subjected to acceptance tests before it is put into clinical use. Any new, donated or loaned equipment that emits Ionising or non-Ionising radiation should be acceptance tested by the Leicester Radiation Safety Service in the Clinical Engineering Department.

c) Ensuring Medical Devices intended for use on more than one patient must be able to be decontaminated in line with the UHL Cleaning and Decontamination Policy (B5/2006).

d) Ensuring staff full compliance with Medical Device training requirements.

e) Ensuring that records of medical equipment belonging to their area are maintained.

f) Making provision for the necessary funding for medical equipment acquired via UHL procurement processes, to receive Planned Preventative Maintenance (PPM) in accordance with Clinical Engineering or the Original Equipment Manufacturers (OEM) recommended schedules.

Note: Taking decisions based on advice received from Clinical Engineering relating to the suitability of maintenance providers and the necessary level of maintenance cover for their equipment.

g) Making Medical Device assets available to the selected maintenance agency when PPM is due.

h) Ensuring records of PPM and repair undertaken by external (non – Managed Equipment Schemes (MES)) maintenance agencies are obtained from those agencies and passed to Clinical Engineering for recording on the Trust Medical Device database (eQuip).

i) Ensuring faulty re-usable Medical Devices are cleaned and decontaminated as set out in UHL Guidelines for Cleaning and Decontamination (2006), UHL Policy B5/ 2006 and sent for repair with a completed decontamination certificate that includes all relevant information to enable identification of the fault.

j) Ensuring safety information is communicated to all relevant staff and acted upon

k) Ensuring action is taken to address adverse incidents involving Medical Devices in line with the UHL Policy for the Management of Patient and Staff Safety (A10/2002).

l) Registering medical equipment that includes computing devices which require network connection or remote data storage facility with the IT Department and Clinical Engineering.

m) Ensuring that asset additions forms for items of capital value medical equipment are sent to Finance so that the asset can be added to the Trust's Capital Asset Register.

n) Providing details of disposed assets to Finance and Clinical Engineering; using the asset disposal form.

o) Ensuring there are adequate and suitable storage facilities for Medical Devices that are not in use; e.g. to prevent the devices becoming damaged, lost or maintained in a fully charged state.

p) Ensuring appropriate representatives from their CMG attends the Trust Medical Equipment Executive Committee meetings when required.

4.8 **Clinical Staff** are responsible for:

a) Ensuring they are appropriately trained and assessed as competent in the use of Medical Devices. Staff must not use a device if they are not competent to do so.

b) Reporting any problems or issues with Medical Devices. Adverse incidents involving Medical Devices must be reported through the Datix web system.

Note: Staff must report items of medical equipment found without a Clinical Engineering Tag Number / asset number label attached. Reports must be raised via the Trust Incident Reporting Procedure (i.e. Datix- web incident reporting system).

c) Ensuring faulty equipment is labelled and isolated to prevent its use.

d) Ensuring they follow the Trust's decontamination procedures after use, between patients (unless single use devices) and prior to equipment being returned to the intended maintenance agency.

e) Ensure Medical Devices are appropriately stored when not in use to avoid damage to the equipment, and injury to staff and in a manner to ensure it remains in a working condition when next required, as per paragraph 1.1 of Appendix 6.

f) Following the processes outlined in the appendices to this policy; in particular to comply with procedures for Planned Preventative Maintenance and Repairs as outlined in appendix 5.

g) For ensuring that all devices and medical equipment accepted into the Trust as part of a trial comply with the UHL Policy for the Donation and Loan of Equipment (B19/2004)

h) Ensuring any medical equipment loaned from the Medical Devices libraries are

returned when no longer required.

4.9 **Clinical Engineering** are responsible for:

a. Working closely with the MEE and CMGs to provide advice and support on all matters relating to Medical Devices.

b. Working closely with other groups of equipment experts within UHL (see table 1 below) to ensure relevant governance (see section 5) around Medical Device management is adhered to:

Equipment Type	**Equipment Service Agent**	**Equipment Inventory Management System**
Scales	Manual Handling	Excel Spreadsheets
Beds/Mattresses	Medstrom via Manual Handling (MES*)	Medstrom propriety system
Manual Handling Equipment	Manual Handling/ Clinical Engineering	eQuip
Radiology Equipment	Althea via Medical Physics (MES*)	Althea bespoke inventory system.
Renal Replacement Therapy	Renal Technical Services	eQuip
Radiotherapy**	Radiotherapy Technical Services	Q-Pulse
Surgical Instruments (including surgical drills instruments)	Synergy via Trust Decontamination lead (MES*)	Steris propriety system
Pathology Equipment***	Maintenance Contracts Managed by Pathology	Q-Pulse
POCT Equipment	POCT/ Clinical Engineering	eQuip
Operating Lights/Pendants	Estates	eQuip
All Other Equipment	Clinical Engineering	eQuip

Table 1: UHL Equipment Service/management agents and Inventory System for maintenance records

***** Managed Equipment Service

** Some items of Radiology Equipment not covered by the MES scheme is managed by Clinical Engineering

*** Out of scope of this policy

c. Administering the Trust Medical Devices database (eQuip); an inventory of Medical Equipment as per section 3.6.

d. Maintaining a schedule of PPM arrangements for all Medical Devices they manage, on the eQuip database, and for informing CMG's of any gaps in PPM

cover; requesting action plans from the equipment owner to address such shortfalls.

e. Working closely with equipment experts (table 1), CMG's, Finance & Procurement to ensure value for Money when procuring equipment.

f. Supporting equipment owners in relation to the suitability of external maintenance contracts offered by external parties.

g. Assisting equipment owners to dispose of obsolete and unwanted medical equipment via safe and appropriate disposal routes to ensure that WEEE (Waste Electrical and Electronic Equipment Regulations) and Information Governance regulations are adhered to. Refer also to Appendix 8.

h. Along with other internal equipment experts, ensuring any in house PPM is performed in accordance with justified risk-based schedules.

i. Recording jobs undertaken by external (non – Managed Equipment Schemes (MES)) agencies (e.g., for PPM and Repair) for equipment recorded on the eQuip database.

j. The Trust Radiation Protection Adviser is responsible for all issues relating to equipment which produces Ionising or non-Ionising radiation.

k. Working closely with other equipment experts (table 1) on advising/supporting equipment users and/or project managers on strategic/local projects regarding Medical Devices, such as connectivity of Medical Devices to Trust IT systems, or the tracking of Medical Devices, or proving scientific support with incident investigations.

5. POLICY IMPLEMENTATION AND ASSOCIATED DOCUMENTS –WHAT TO DO AND HOW TO DO IT

The requirement of this policy is to ensure that Medical Devices used within the Trust, or by Trust staff used outside the Trust are:

- Clean and available for use when required
- Secure
- Suitable for the purpose for which they are being used
- Properly used
- Properly maintained
- Disposed of appropriately when no longer fit for purpose.

This policy covers all Medical Device activities at UHL (Appendix 1).

Dissemination of this policy will be via MEE, whose CMG representatives will distribute through their local CMG governance forums.

Associated documents related to this policy, are available on UHL Connect or the MHRA website are:

- Trust Capital Equipment Asset Addition form
- Trust Capital Equipment Disposal form

- Trust Capital Equipment Transfer form
- Loan and Donation forms
- Trust PAQ
- Urgent Capital Equipment Bidding form
- Yellow Card MHRA reporting form
- Decontamination Status form (W804)

6 EDUCATION AND TRAINING REQUIREMENTS

6.1 There is no mandatory training requirement relating to this policy. Appendix 4 details requirements in terms of Medical Device user training.

7 PROCESS FOR MONITORING COMPLIANCE

Element to be Monitored	Lead	Tool for Monitoring	Frequency	Reporting Arrangements
Review incident reports relating to Medical Devices	Medical Device Safety Officer	Datix, eQuip	Bi-monthly	Medical Equipment Executive / UHL Medical Device Safety Group
Maintenance uptake and repair turnaround times for equipment managed by Clinical Engineering	General Manager Medical Physics	Medical Equipment Management Service (CE) KPI's	Monthly	CSI Performance & Assurance meetings
Equipment is decontaminated prior to transferring to Clinical Engineering	Head of Clinical Engineering	Decontamination form checked by Clinical Engineering team prior to accepting the equipment for service	Per transfer	Return to CMG if incomplete
Actual Training compared to Required Training	Medical Device Training Manager	Medical Device Training Record system	Monthly Bi-monthly	To CMG HoN To MEE

8 EQUALITY IMPACT ASSESSMENT

8.1 The Trust recognises the diversity of the local community it serves. Our aim therefore is to provide a safe environment free from discrimination and treat all individuals fairly with dignity and appropriately according to their needs.

8.2 As part of its development, this policy and its impact on equality have been reviewed and no detriment was identified.

EDI Statement

We are fully committed to being an inclusive employer and oppose all forms of unlawful or unfair discrimination, bullying, harassment and victimisation.

It is our legal and moral duty to provide equity in employment and service delivery to all and to prevent and act upon any forms of discrimination to all people of protected characteristic: Age, Disability (physical, mental and long-term health conditions), Sex, Gender reassignment, Marriage and Civil Partnership, Sexual orientation, Pregnancy and Maternity, Race (including nationality, ethnicity and colour), Religion or Belief, and beyond.

We are also committed to the principles in respect of social deprivation and health inequalities.

Our aim is to create an environment where all staff are able to contribute, develop and progress based on their ability, competence and performance. We recognise that some staff may require specific initiatives and/or assistance to progress and develop within the organisation.

We are also committed to delivering services that ensure our patients are cared for, comfortable and as far as possible meet their individual needs.

9 SUPPORTING REFERENCES, EVIDENCE BASE AND RELATED POLICIES

- UHL Work Equipment – B8/2004
- Policy for the Donation and Loan of Equipment – B19/2004
- Guideline for the Medical Equipment Capital Allocation Process – B4/2014
- Guideline for the Management of Medical Devices for Research and Development - B19/2013
- Information Security UHL Policy – A10/2003
- Cleaning and Decontamination for Infection prevention – B5/2006
- UHL Ionising Radiation (Medical Exposures) Regulations 2017, UHL Policy B13/2001
- Central Alerting System (CAS) Broadcasts Policy UHL Central Alerting System (CAS) Safety Alerts Management Policy – B1/2005
- Incident and Accident Reporting UHL Policy - A10/2002
- Space Utilisation and Allocation Policy B18/2014

This policy takes into account guidance available nationally, including that from the MHRA. The principal guidance documents currently available from the MHRA are:

Managing Medical Devices

For the maintenance Risk Assessment of Medical Devices, IPEM report 95 has been referenced in Appendix 9.

For the purposes of procurement of Medical Devices and for in-house developed and used (IHDU) Medical Devices the following document is referenced:

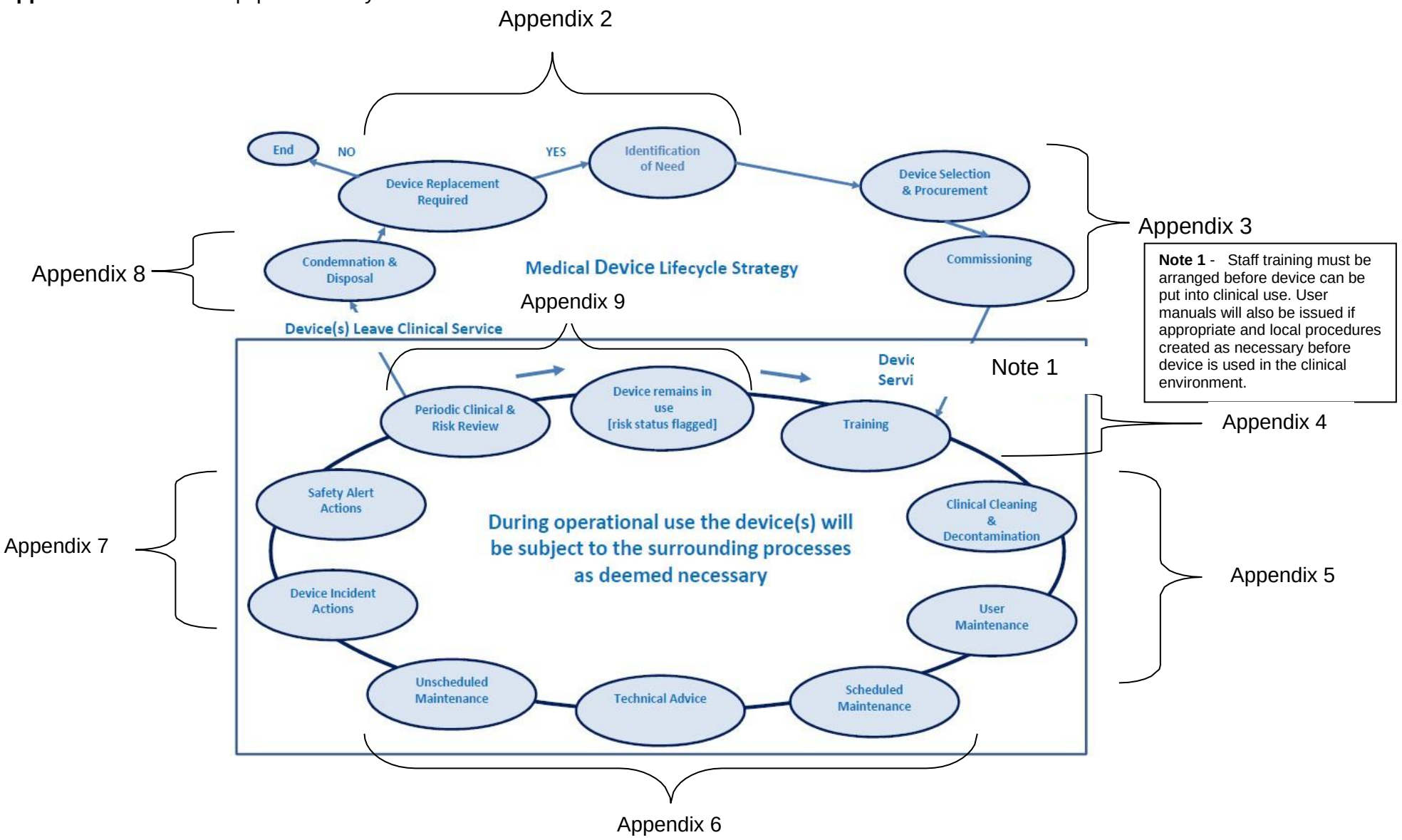
Medical Device Directive 93/42/EEC

10 PROCESS FOR VERSION CONTROL, DOCUMENT ARCHIVING AND REVIEW

10.1 This policy will be reviewed every three years or more frequently as designated by the Medical Equipment Executive.

10.2 Previous electronic versions are archived on 'SharePoint' (previously DMS). Staff working at the local level are responsible for destroying paper copies of previous iterations of this policy.

Appendix 1 – Medical Equipment Lifecycle Process Flowchart



Appendix 2 – Medical Equipment Acquisition

1. Introduction

1.1. All equipment purchases shall be made in accordance with the Standing Financial Instructions of the Trust. Advice relating to the selection and procurement of Medical Devices can be sought from the Procurement and the Clinical Engineering Department, or other equipment experts (table 1).

2. Capital Medical Equipment (>£5k expenditure)

2.1. The committee structure for assessing and prioritising bids for capital medical equipment, maintaining replacement programmes and allocating capital funds on behalf of the Trust Board is illustrated in Appendix 11.

2.2. CMG's present prioritised bids for new and replacement capital medical equipment to the Medical Equipment Panel (MEP).

2.3. The Capital Monitoring and Investment Committee (CMIC) determines the allocation of capital funds to the Medical Equipment Executive, Estates and Facilities and IM&T subgroups. These allocations are submitted to the Trust Board for approval. The MEP reviews all cases of need with CMG representatives and recommends priorities for capital medical equipment purchases to the Medical Equipment Executive (MEE). The MEE reviews the recommendations of the CMEPG and approves/endorses these recommendations and formalises a procurement plan for the following financial year.

2.4 MEE requests a capital allocation from CMIC based on the value of the bids received from the CMG's. CMIC allocation is given in the following financial year and MEE oversees the procurement plan. This is finalised once the capital allocation level is known; often this requires the original procurement plan to be revised due to the allocation being different to the sum requested.

2.5 Bids for charitable funds to purchase capital items of medical equipment must also be referred to the Chair of the Medical Equipment Executive (MEE) to ensure that the purchase fits with the Trust's capital medical equipment programme and / or Trust 5-year plan.

2.6 The MEE also considers in year bids for emergency funding of replacement items requiring capital investment. Such items will either be obsolete and no longer supported by the manufacturer or broken beyond economical repair. CMG's will bid for funding on a case-by-case basis as the need arises.

3. Non-capital Medical Equipment (<£5k expenditure)

3.1. CMG's are responsible for funding the purchase of new and replacement non-capital Medical Devices. However, CMG's will also be invited to highlight any significant non-capital equipment needs to the MEE.

3.2 Where there is a Trust wide need to replace such devices, because of an established risk, obsolescence or where clear benefit would be realised, the MEE will consider cases for centrally funded purchasing programmes.

3.3 If the Trust is able to make available central funds, then a procurement process will be overseen by the Medical Equipment Executive. The MEE will prioritise suitable cases for

non-capital Medical Device purchase. Standardisation of models of equipment will be at the heart of this process.

4. IT and Building Services Requirements

4.1 Some types of medical equipment include standard computing devices (e.g. a PC) or have a requirement for network connections or data storage. Proposals to buy such equipment should be referred to the IM&T Department and/ or the Privacy Unit (for queries relating to devices concerning patient data storage) to ensure that these requirements can be met, and that the equipment is compatible with existing Trust IM&T equipment. Where the device is capable of producing output that may form part of an "electronic patient record", discussion should be held with IM&T over patient identification, numbering and interfacing, etc. Initial contact with IM&T for all matters relating to medical equipment computing issues should be made via the UHL IM&T Helpdesk.

Note: Refer also to UHL Information Security Policy – A10/2003 (section 5.18 specifically applied to Medical Equipment).

Some types of medical equipment may consume significant electrical power or require connection to other mains services such as water or medical gases or require environmental control (e.g., air conditioning). Equipment of this type

4.2 should be discussed with the Estates Directorate, prior to purchase, to ensure suitable facilities can be provided to support these special requirements, and costings are considered.

4.3 Where the acquisition of medical equipment may constitute a change of use of a room / facility, the CMG must also refer to the Trust's space policy, to ensure that the location is suitable for the intended purpose.

This will then invoke a review of a broad range of Estates and facilities related issues, such as the need for a change in the IP / cleanliness requirements, critical ventilation, etc.

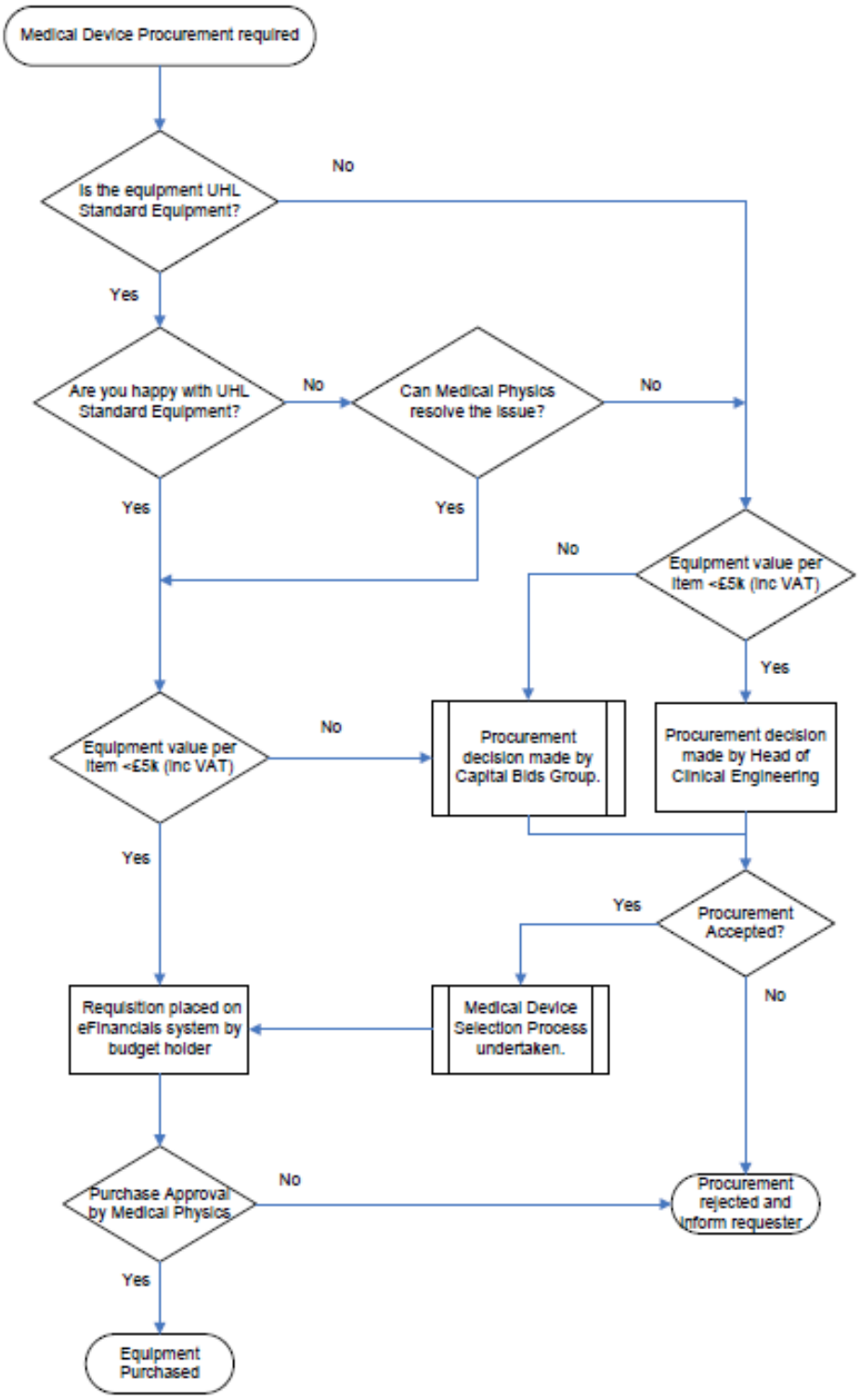
Appendix 3 – Procurement and Standardisation of Medical Equipment, and associated accessories and consumables, and the commissioning of Medical Devices.

1. Selection and Procurement of Medical Devices

1.1 To reduce risks arising from inadequate user training, high risk Medical Devices intended for common applications must, where possible, be standardised. Other common Medical Device types should also be standardised to reduce costs and risks. All orders for electrically operated Medical Devices must be approved by the Clinical Engineering Department or associated equipment expert (table 1), and the Trust Medical Device decontamination lead through the purchase approval procedure, to ensure compliance with this policy.

1.2 The process for the procurement of Medical Devices is outlined in flowchart 1 below:

Flowchart 1



1.3 Requests for alternative models to those that are UHL standard models for that category of equipment will be considered by the relevant stakeholders, namely procurement, clinical engineering and decontamination leads, taking into account clinical requirements and risks, technical specification, compliance with Trust decontamination protocols and purchase and whole life costs.

1.4 Where requests for new models is rejected the head of clinical engineering will write to the requester detailing the rationale for the model being rejected and provide details of alternative models that are available.

1.5 Details of standard models can be provided by the head of clinical engineering;

1.6 The process for determining the UHL standard model or requesting consideration of a change to the standard model is outlined in flowchart 2 below.

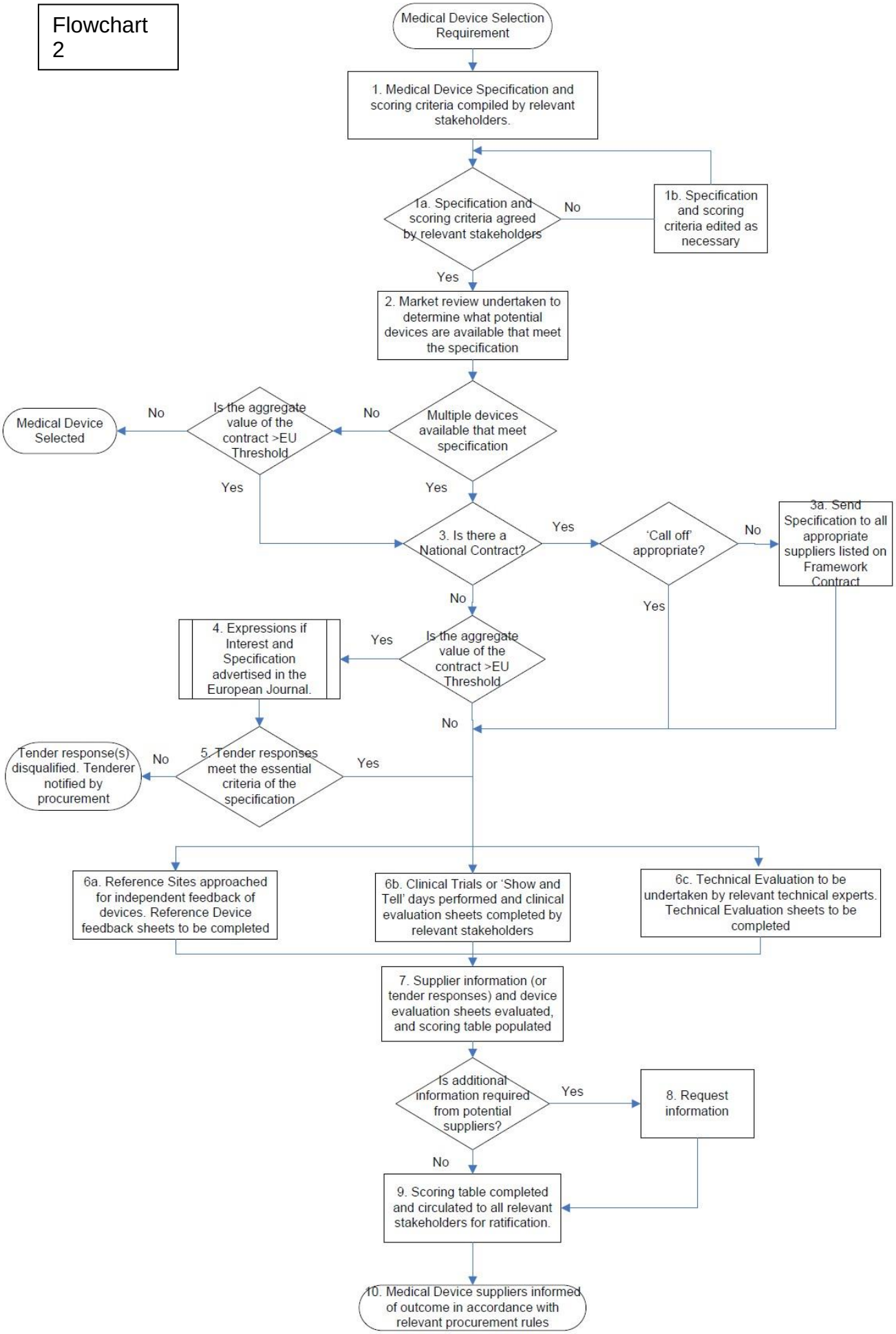
1.7 Clinical Engineering or associated equipment expert (table 1) are available to assist the requestor at all stages of the process, e.g. specification writing, market assessment. Other groups such as IM+T and Facilities may also need to be involved dependent upon the type of equipment involved and its operational requirements.

1.8 The requestor will appoint a Selection Lead to interact with all stages of the process; including leading the clinical evaluation stage.

1.9 The technical evaluation stage will be performed by the appropriate in-house expert (e.g. Clinical Engineering, Renal and Radiotherapy Physics); who will work in collaboration with the Selection Lead.

1.10 Procurement will lead on contract and tender stages. All purchases will be made in line with Trust Standing Financial Instructions.

Flowchart 2


Medical Device Selection Requirement
1. Medical Device Specification and scoring criteria compiled by relevant stakeholders.
1a. Specification and scoring criteria agreed by relevant stakeholders
No
1b. Specification and scoring criteria edited as necessary
Yes
2. Market review undertaken to determine what potential devices are available that meet the specification
Multiple devices available that meet specification
No
Is the aggregate value of the contract >EU Threshold
No
Medical Device Selected
Yes
Yes
3. Is there a National Contract?
Yes
'Call off' appropriate?
No
3a. Send Specification to all appropriate suppliers listed on Framework Contract
Yes
No
Is the aggregate value of the contract >EU Threshold
Yes
4. Expressions if Interest and Specification advertised in the European Journal.
No
5. Tender responses meet the essential criteria of the specification
No
Tender response(s) disqualified. Tenderer notified by procurement
Yes
6a. Reference Sites approached for independent feedback of devices. Reference Device feedback sheets to be completed
6b. Clinical Trials or 'Show and Tell' days performed and clinical evaluation sheets completed by relevant stakeholders
6c. Technical Evaluation to be undertaken by relevant technical experts. Technical Evaluation sheets to be completed
7. Supplier information (or tender responses) and device evaluation sheets evaluated, and scoring table populated
Is additional information required from potential suppliers?
Yes
8. Request information
No
9. Scoring table completed and circulated to all relevant stakeholders for ratification.
10. Medical Device suppliers informed of outcome in accordance with relevant procurement rules

2. Safety and Performance

2.1 Before an order is placed, prospective suppliers of Medical Devices to the Trust will be required to demonstrate that their equipment is safe and suitable for its intended purpose and that it can be cleaned and decontaminated between patient episodes. Information on compliance with relevant technical standards, EC directives and decontamination methods will be requested by the Clinical Engineering Department through use of the Pre-Acquisition Questionnaire (PAQ). Medical devices supplied to the Trust must meet the essential requirements of the Medical Devices Regulations.

2.2 The PAQ procedure is not normally required where the Clinical Engineering Department already holds an approved PPQ/PAQ from a previous purchase of an identical model from the same supplier e.g., for standardised device models.

3. Equipment Acceptance

3.1 All reusable Medical Devices and equipment entering the Trust must undergo acceptance tests, as required by MHRA guidance "Managing Medical Devices" by the relevant in-house technical support service, before being put into use.

3.2 Electrically operated Medical Devices and equipment delivered to the Trust via the Operational Supplies Department will be forwarded to the relevant in-house technical support service for acceptance testing where practicable. CMG's must ensure that items delivered directly to clinical areas are subject to acceptance testing by technically trained staff before use. Labels shall be attached to all items which have been through this process to indicate the date tested and next test due, if applicable.

Note: Devices and Equipment may be tested prior to use by the supplier or associated representative. Where this happens, the work will be overseen by Clinical Engineering or other associated equipment expert (table 1) and the asset added to its associated inventory.

3.3 All medical equipment tested by Clinical Engineering or other equipment expert (table 1) must be recorded on its associated inventory prior to release for use.

3.4 Equipment, which includes standard computing devices (e.g., a PC) that requires network connections or remote data storage facilities, should be registered with the IM&T Department (refer to Appendix 2).

3.5 For equipment which generates Ionising radiation, it is the duty of the installer to carry out a critical examination of the radiation safety features of the equipment in accordance with the Ionising Radiation Regulations 2017 (IRR17). The Clinical Engineering Department will carry out acceptance tests on behalf of the Trust. For further advice on radiation safety, users should contact the Leicester Radiation Safety Service in the Clinical Engineering Department.

3.6 For Information on the loan, donation and free issue of medical equipment refer to the UHL Policy - Loan and Donation of Equipment - B19/2004.

4. Selection and procurement of consumables and accessories

4.1 Medical Equipment often requires consumables and accessories to perform their intended function. A definition of an accessory and consumable is given in section 3 of

this Policy.

4.2 When required, Original Equipment manufacturer (OEM) approved consumables and accessories should be used, unless:

- An alternative is approved by the CMG best value group and/or the medical equipment standardisation group
- There remains significant evidence from historical use of a specific alternative product, that Medical Devices perform as intended with the non-OEM approved consumable or accessory.

4.3 A number of company's now supply a range of consumables and accessories for medical equipment. Accessories or consumable not directly or indirectly supplied by the OEM's are classed as a third-party accessories/consumable.

4.4. Many third-party consumables and accessories are already successfully used with medical equipment within UHL for a number of reasons, with main emphasis being value for money. However there have been a number of incidents reported nationally where the intended function of Medical Devices have been impacted by use of third-party consumables and accessories.

4.5. As such the following process shown in flowchart 3 shall be followed when any new third-party consumables and accessories are being considered for use with UHL Medical Devices.

5. The management of Spare parts and Batteries used on Medical Devices

5.1. Types and quantities of medical equipment spare parts held in stock by the internal service provider should be optimised to minimise on-site stock holdings (thereby reducing expenditure, wastage and storage requirements), whilst holding sufficient stock to achieve minimal equipment servicing downtimes (i.e. avoiding equipment servicing delays resulting from unavailability of necessary parts/consumables).

5.2 Decisions upon types and quantities of stock held should be based upon considerations of criticality, demand and availability.

5.3 Inventory management should ensure traceability of spare parts and their usage in equipment servicing. Parts and components used during servicing activities should be identifiable in the equipment's servicing history; any critical parts used need to be delivery-referenced and individually traceable to the original supplier in equipment servicing records. Parts that are uniquely identifiable (e.g.: by individual serial number) should have this detail recorded.

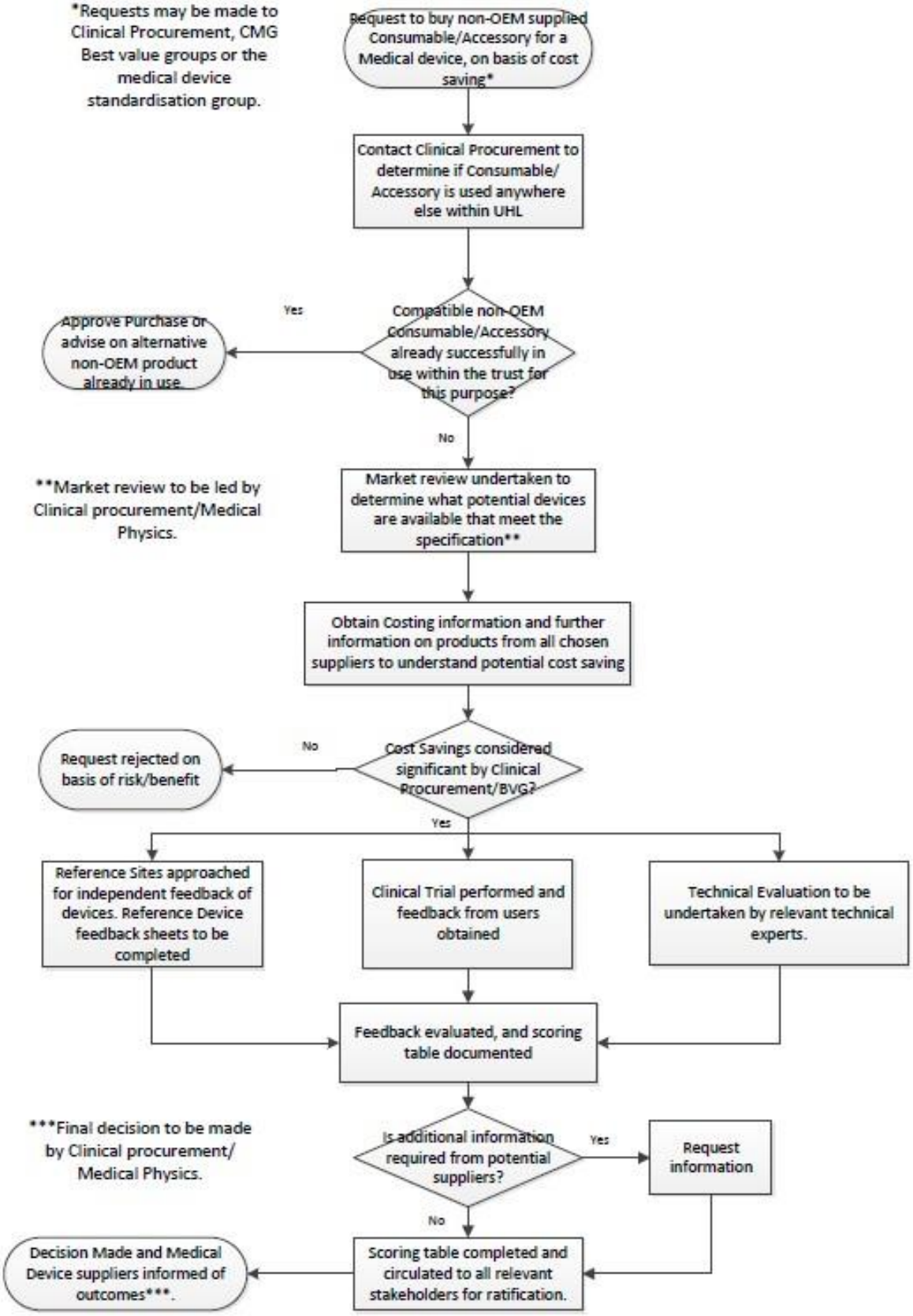
5.4 Manufacturer approved spare parts and consumables should be used in the servicing of Medical Equipment. Any use of non-OEM approved spare parts requires approval on the basis of a full documented cost analysis and risk assessment, performed by a competent person and signed off by CMG exec or alternative committee, to ensure compatibility with specifications and that any associated risks are understood, acceptable and can be controlled (as per section 4 above).

5.5 Where alternative batteries are being considered for use with Medical Devices, that are not approved by the OEM, and that have not been used previously, and no historical evidence of their compatibility exists, a full documented cost analysis and risk assessment, shall be performed and approved by a competent person, to ensure

compatibility with specifications, and that any associated risks are understood and managed (as per section 4 above).

5.6 The use of pre-use spare parts from redundant Medical Devices should be avoided unless no alternative exists, or the spare part does not affect the function of the device e.g. external case, caster, handle. Pre-use spare parts may be acceptable in exceptional circumstances after a fully documented risk assessment approved and accepted by a competent person.

Flowchart 3


*Requests may be made to Clinical Procurement, CMG Best value groups or the medical device standardisation group.
Request to buy non-OEM supplied Consumable/Accessory for a Medical device, on basis of cost saving*
Contact Clinical Procurement to determine if Consumable/ Accessory is used anywhere else within UHL
Compatible non-OEM Consumable/Accessory already successfully in use within the trust for this purpose?
Yes
Approve Purchase or advise on alternative non-OEM product already in use.
No
**Market review to be led by Clinical procurement/Medical Physics.
Market review undertaken to determine what potential devices are available that meet the specification**
Obtain Costing information and further information on products from all chosen suppliers to understand potential cost saving
Cost Savings considered significant by Clinical Procurement/BVG?
No
Request rejected on basis of risk/benefit
Yes
Reference Sites approached for independent feedback of devices. Reference Device feedback sheets to be completed
Clinical Trial performed and feedback from users obtained
Technical Evaluation to be undertaken by relevant technical experts.
Feedback evaluated, and scoring table documented
***Final decision to be made by Clinical procurement/ Medical Physics.
Is additional information required from potential suppliers?
Yes
Request information
No
Scoring table completed and circulated to all relevant stakeholders for ratification.
Decision Made and Medical Device suppliers informed of outcomes***.

6. Inventory management

6.1 Medical Device Inventories

6.1.1. New items of medical equipment will be recorded on its associated inventory (table 1).

6.1.2 In accordance with the Trust 'Standing Financial Instructions' budget holders shall inform finance about all new items of medical equipment purchased as part of a Capital Scheme, or via the Capital Medical Equipment Panel. These items shall also need to be recorded on the Trust Capital Equipment financial asset register by completing a Capital asset form (available from Finance) and sending this to Capital finance.

6.1.3 The addition of each new asset to the associated inventory updates the overall inventory of reusable diagnostic and therapeutic Medical Devices that the Trust owns, has on loan or has had donated to it.

Note: the eQuip inventory does not include items of medical equipment that are used in the Trust but managed by a dedicated supplier.

Examples include.

Radiology Equipment - provided and maintained by Althea

Beds, Therapy Pressure Relieving and Foam mattresses, couches – provided and maintained by Hill-Rom (under subcontract by Medstrom)

Surgical Instruments – managed (decontaminated and maintained) by Synergy

Note: The inventory may also exclude small, low-cost devices such as stethoscopes.

6.1.4 Records of any calibration, repair and Planned Preventative Maintenance (PPM) events undertaken on equipment shall also be recorded on the associated inventory; to build a unique account of the equipment's life history.

6.1.5 The asset history record will be closed and archived when the asset is removed from use. Records of end-of-life decisions, e.g. disposal / mothballing / redistribution, will also be made on associated inventory.

6.2 Relocation of Medical Devices

6.2.1 Equipment owners must inform the Clinical Engineering Department or associated equipment experts (table 1) of any changes to the status of equipment such as long term (>1 month) relocation, modification or disposal. This will ensure the associated inventory is maintained accurately when changes in the clinical environment occur.

6.2.2 Device owners / Clinical Area Managers / Equipment Managers must inform Finance of any changes in the permanent location of their capital assets via an Asset Transfer Form, which is available via the Finance Department.

6.2.3 Devices transferred between sites must be tested for electrical safety by Clinical Engineering or other associated equipment experts (table 1) before being used clinically at its new location; to ensure that the device remains fit for purpose.

6.2.4 Device owners / Clinical Area Managers / Divisional Equipment Managers are strongly discouraged from moving non-standard models of equipment between different locations. If this cannot be avoided due to clinical requirements, then the impact of end user training must be taken into consideration.

Appendix 4 – Medical Device User Training

1. All members of staff are trained in the safe and effective use of devices through a combination of work placements during qualification, local inductions, clinical skill specialist-led sessions and new device introduction.
2. Line managers should identify Medical Device usage within their clinical areas. This should be mapped against staff roles. Individual skill level compared to the role requirement represents the training needs.
3. Staff skill in device use is assessed by practice observation and specific competency assessments.
4. Observations and assessments are carried out by senior nursing and midwifery registered staff, clinical skills specialists, Medical Device Training team and manufacturers.
5. Training is provided by manufacturers, Medical Device training team, super users, clinical skills specialists.
6. Training sessions from the device manufacturer form the basis of what staff need to know. A summary of this information will be available for all staff to view on the Medical Devices training webpage on UHL Connect. Competency assessments shall be made by using these documents.
7. Training records are held centrally by Medical Devices training team for all training made known to or delivered by the Medical Device training team.
8. The training records of Medical Devices specific to professional / technical competence associated with registration requirements will be held by the managers of the specialist departments e.g. Physiotherapists, Neurophysiologists, Audiologists etc.
9. MES providers such as Althea and Medstrom shall keep staff training records for equipment within the MES.
10. Clinical Area Managers shall keep Medical Device training records for all staff they manage, that are not covered by 7,8, and 9 above.
11. Staff skill is monitored through self-assessment feedback. Arrangements for improving areas of concern are coordinated by the Medical Device training team.

Appendix 5 – Safe Use and Ownership of Medical Devices

1. Cleaning and Decontamination

1.1 All staff have a duty of care under the Health and Safety at Work Act (1974) to avoid exposing themselves, patients and other staff to dangers that may arise in their working environment. Medical devices are potential carriers for disease; producing microbes and may provide a vehicle for cross infection between patients. The risk of cross infection is high for Medical Devices used in contact with non-intact skin or body fluids, or entering a sterile body cavity. It is essential that Medical Device users apply the Trust's policy (B5/2006) on Cleaning and Decontamination of Medical Devices. All Medical Devices must be cleaned and decontaminated between patient episodes in accordance with this policy to reduce the risk of cross infection.

1.2 All staff transferring Medical Devices to Clinical Engineering or associated equipment experts for maintenance or repair must be accompanied by the latest version of the UHL decontamination status form (W804), or the form maybe completed on-line if the job request is completed on-line. Hard copies of this form are available from The Operational Supplies Department, Materials Handling Unit.

2. Single Use Medical Devices

2.1 Medical devices identified as single use are intended to be used on an individual patient during a single procedure and then discarded. It is not intended that they be reprocessed and used again, even on the same patient. The following symbol is used on the packaging of single use Medical Devices to indicate that they must not be reused.

Details on the use of single use Medical Devices are given in UHL Cleaning and Decontamination Policy B5/ 2006.

3. Transport of Equipment

3.1 Persons arranging the transport of Trust equipment must ensure that any equipment, which has been subjected to abnormal stresses (e.g. dropped, involved in collision, fluid ingress) during transport, is tested by the Clinical Engineering Department, or associated equipment experts before being put into use.

3.2 In addition, equipment on loan to the Trust must not be transferred from the hospital site which received it without first ensuring it is within the agreement of the supplier to do so.

4. User Maintenance

4.1 The distinction between medical equipment operational management and medical equipment servicing should be understood. The various operational equipment upkeep requirements, (i.e.: any specified routine cleaning, adjustment, functional

checks, quality control measures, etc.), are user tasks – often collectively referred to as Routine (User) Maintenance.

4.2 Responsibility for performance of these rests with Ward Sisters / Charge Nurses.

4.3 During equipment user training, users shall be provided with the necessary information to perform these functions.

5. Medical Device Libraries

5.1 The Medical Equipment Library (MEL) Service is well-established at Glenfield Hospital (Between AICU and Main Theatres), Leicester General Hospital (Clinical Engineering Workshop) and the Leicester Royal Infirmary (Victoria Basement) under the management of Clinical Engineering;

5.2 Clinical Engineering have a designated team of library staff that delivers a managed equipment loan service, providing access to a range of medical equipment kept in states of preparedness for use, (in terms of cleaning, battery recharging, pre-use testing, etc.).

5.3 The potential benefits of MEL are widely recognised; in addition to promoting efficient Utilisation and hence optimised acquisition planning for medical equipment, with beneficial economic consequences, these include –

- Improved equipment availability for users, inclusive of a daily stocked pump store for the portering service to supply pumps out of hours;
- Effective utilisation in clinical areas using non identifying data to allocate pump to patient and prevent storage of pumps not in use in clinical areas
- Reduced equipment damage and loss due to safe, managed storage and retrieval procedures
- Regular condition inspections
- Improved access to medical equipment for servicing
- Facilitation of equipment standardisation
- Improved patient safety as a consequence of the above.

5.4 In order to ensure the above benefits are realized, the users of the service have a responsibility to ensure equipment managed by the MEL is returned to the MEL collection points when no longer required, as to avoid hoarding and reduced access.

5.5 UHL is committed to the continued development and improvement of the Medical Equipment Library Service, which is primarily used for infusion devices. However Clinical Engineering encourages identification of additional types of Medical Equipment which, in consideration of the nature and range of their usage and operational management requirements, could benefit from inclusion in the library services.

6. Medical Devices Issued to Patients/Carers

6.1 When devices are issued by the Trust to patients, relatives, carers or other end-users, then Trust staff arranging device provision must ensure that the end-user understands the intended use and normal functioning of the device and has received appropriate training on its use and upkeep and has been given written instructions.

6.2 The end user must be provided with appropriate contact details for an advisor within the Trust, to whom they can refer in the event of queries or problems arising; they should also be instructed to contact the advisor immediately if they suspect any device malfunction.

6.3 Trust staff arranging device provision to patients/carers when they are discharged must ensure users are aware when PPM is required on the device (if appropriate) and the procedure for ensuring this is completed by the date due.

Appendix 6 – Maintenance and Repair of Medical Devices

1. Maintenance arrangements

1.1 Storage arrangements for equipment not in use should be adequate to safely accommodate the volume of equipment being housed and designed to minimise the risk of damage, battery deterioration and loss of accessories.

1.2 Medical device categories will be risk assessed for their maintenance needs by the UHL Clinical Engineering department (see appendix 9). Medical devices identified as medium/high risk must be prioritised for scheduled Planned Preventative Maintenance (PPM).

1.3 At a minimum all low-risk Medical Devices will be electrically safety tested (EST) in accordance with risk-based intervals; defined by the UHL Clinical Engineering, or other associated equipment expert (table 1)

1.4 Suitable maintenance arrangements must be in place for all Medical Devices. This includes purchased, leased, managed and free issue equipment. CMG's are responsible for selecting the maintenance option / agency (e.g. OEM, Clinical Engineering, other internal service provider) that will support their equipment.

1.5 Clinical Engineering will notify owners of medium/high risk equipment where no arrangements for PPM exist and provide advice regarding the PPM options available.

1.6 It is the responsibility of the budget holder to ensure appropriate PPM arrangements are chosen and funded.

Note: The Medical Equipment Executive may request action plans from CMG's to address shortfalls in PPM cover. Where plans are not produced or are not fulfilled, within a 3-month period, the Medical Equipment Executive will refer the matter to EQB.

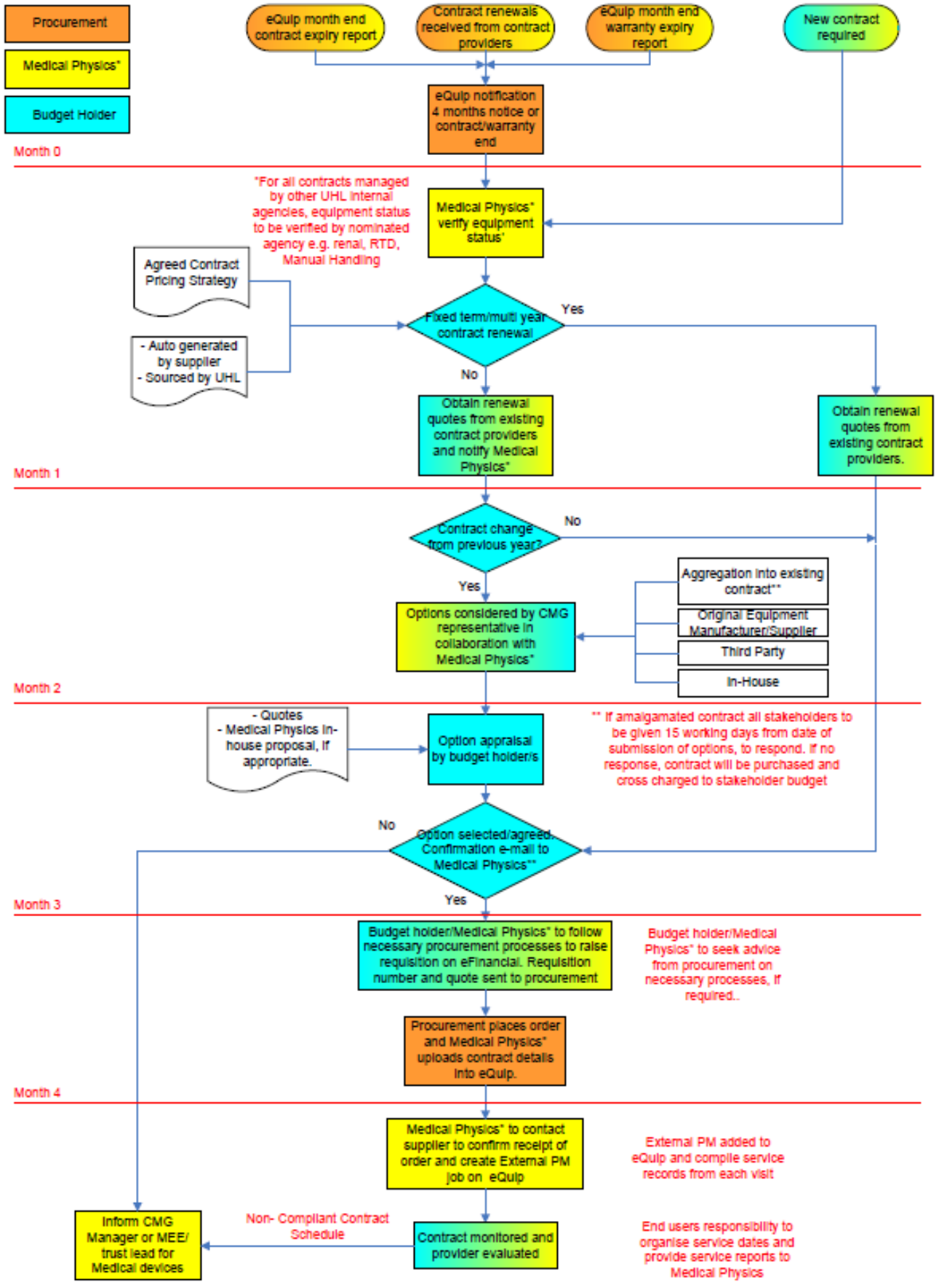
1.7 External maintenance arrangements will be made via contractual agreement with an appropriate supplier as per flowchart 4 below.

1.8 Procurement will provide Clinical Engineering with details of any external maintenance agencies chosen by CMG's in order for the relevant information to be captured on eQuip.

1.9 CMG's must ensure records are received for all maintenance work (planned and repair) undertaken by external providers and are provided to Clinical Engineering for recording onto the Trust medical equipment database eQuip, unless they have a local electronic system for service history management.

1.10 In-house PPM schedules for Medical Devices must be performed in accordance with the recommendations of the Original Equipment Manufacturer (OEM); whoever the chosen maintenance provider, unless sufficient evidence is available to justify deviations from this, which are agreed by all stakeholders

Flowchart 4 – Supplier Maintenance



2. Medical device upgrades and Modifications

2.1 All Medical Equipment upgrades, and modifications must be executed according to manufacturer instructions. Equipment safety performance assurance testing must be undertaken before returning the upgraded/modified equipment to service. This may be completed by the external service agent undertaking the upgrade/modification or by Clinical Engineering or associated equipment experts.

2.2 If the device upgrade/modification is required on the basis of patient safety, Clinical Engineering or the associated equipment expert (table 1) is responsible for ensuring that changes are implemented within an appropriate timescale (according to considerations of safety and/or operational urgency) and should assess the implications of the equipment changes and communicate these to users as necessary.

2.3 If there are a number of devices of the type to be upgraded/modified, and an unavoidable period over which both modified and un-modified equipment will be in service, then the consequences should be risk assessed and managed accordingly, led by the Senior Clinical Person on duty in the area where the device is being used.

2.4 Any equipment modifications not approved by the manufacturer constitute re-manufacturing, and as such are subject to the requirements detailed in appendix 10.

3. Periodic Inspection of Medical Equipment

3.1 Equipment owners / users must ensure that all medical electrical equipment in their clinical area is inspected prior to use by users, and any defects, which may compromise its safety or function, are reported to the normal maintenance agency (table 1).

4. Equipment Repair

4.1 When malfunction of an item of medical equipment is identified or suspected, the normal maintenance agency (table 1) should be contacted to investigate. In some cases that equipment may need to be removed from service immediately if considered by equipment experts and/or local management, to be a risk to patients and/or staff. In these circumstances the item must be removed from service immediately and labelled clearly to prevent further use. In some cases, if the malfunction is identified in a large batch of devices or a certain parameter of a multi-parameter device, and no alternative device is available, a dynamic risk assessment should be undertaken by the Senior Clinical Person on duty in the area where the device is being used and Clinical Engineering / equipment experts to determine whether it is appropriate to leave the device(s) in use until an appropriate resolution to remedy is agreed and implemented. This should be reported on the Datix incident reporting system.

4.2 All items sent for repair must be accompanied by a completed Equipment Service Request / Decontamination Status Certificate (W804) or electronic decontamination form if request made on-line. Hard copies of this form are available from the Operational Supplies Department, Materials Handling Unit.

4.3 For assets being sent to an external maintenance agency for repair, a copy of the decontamination form (W804) must be sent to Clinical Engineering or other local equipment experts.

5. Managed Equipment Services

5.1 For Medical Devices supplied to the Trust under a managed service contract e.g. imaging equipment, beds and surgical instruments, the service provider will maintain inventories of the equipment on Trust sites and make the inventory information available to relevant Trust staff when required.

5.2 Managed Equipment Service contract suppliers will, upon request from the Trust, provide records of repairs, PPM (including electrical safety testing records) and training records for technical staff involved in delivering their service.

5.3 Managed Equipment Service contract suppliers are required to comply with Trust policies and procedures, that are relevant during the course of providing their service and / or identified in the schedules of their contract with UHL.

5.4 Management Equipment Service contract suppliers shall manage safety alerts and incident investigations for equipment within their associated contract as per Appendix 7.

Appendix 7 – Safety Alerts and Incident Investigations

1. Communication of Safety Information

1.1 Medical Device safety information is received into the organization in a variety of forms, including Alerts from NHSE/I and MHRA and Field Safety Notices (FSN's) issued by equipment suppliers. All alerts are triaged respectively and distributed to (relevant) CMGs and Services via the UHL Central Alerting System (CAS) in accordance with the Policy for the Management of CAS Alerts (UHL Policy B1/2005). CMG representatives must ensure that such information is disseminated promptly to relevant individuals in their area of responsibility and that any recommended actions relating to medical equipment are implemented. All such actions must be recorded and reported back to the Trust's CAS Team.

1.2 For technical advice relating to the safety of medical equipment, users should contact their local Clinical Engineering workshop or other associated equipment experts. For advice on any other safety issues, users should contact their local Health & Safety Adviser.

2. Incident reporting

2.1 All incidents involving medical equipment and associated accessories, must be reported through the Trust's Incident Reporting Procedure, i.e. Datix-web incident reporting system (available via the Trust intranet).

2.2 When an incident occurs with medical equipment either the Clinical Engineering, or other associated equipment experts should be contacted to investigate. In some cases that equipment may need to be removed from service immediately if considered by Clinical Engineering or associated equipment experts and/or local management, to be a risk to patients and/or staff. In these circumstances the item must be labelled clearly to prevent further use. The device shall remain out of use until investigation is complete and any remedial action completed and should only be returned to use on approval from the Clinical Engineering, or other associated equipment expert.

2.3 In some cases, if a potential issue is identified in a large batch of devices or a certain parameter of a multi-parameter device, and no alternative device is available, a dynamic risk assessment should be undertaken by the Senior Clinical Person on duty in the area where the device is being used in conjunction with Clinical Engineering / associated equipment experts to determine whether it is safe to leave the device(s) in use until an appropriate resolution is agreed and implemented. This should be reported on the Datix incident reporting system.

2.4 If UHL owned medical equipment is found without an inventory tag / asset number label attached, it must be reported via the Datix-web incident reporting system.

2.5 The aim of the adverse incident reporting procedure is to prevent reoccurrence. Any incident related to the design or operation of the device, should be reported to the MHRA via the Trust's Medical Device Safety Officers (MDSOs); who act as the MHRA Liaison Officer.

2.6 The Trust MDSO will review Datix incidents and equipment repair requests involving Medical Devices, to look for trends. All suspect repeated Medical Device incidents/reported faults should be discussed at the trust MDSG meetings, where action plans are agreed by the Group in conjunction with CMG management. A summary of Medical Device incidents and associated investigation status should be reported to CMGs via relevant Q&S reports. For trust wide issues, notifications may be communicated via written reports presented by the CSI Nursing lead at Nursing Executive meeting

Appendix 8 – Medical Equipment Disposal

1. No Medical Equipment should be decommissioned or disposed of by whatever means, without notifying Clinical Engineering or associated equipment experts.

2. In addition to the above, notification of all Capital Medical Equipment disposal should be made to the Capital Finance Team by the budget holder prior to any disposal taking place.

3. Reasons for equipment decommissioning may include –

   - loan equipment that has reached the end of its indemnified loan period.
   - equipment involved in completed clinical research, (whether supporting the research or the subject of it),
   - condemned equipment - (condemned because, for example: it does not meet current clinical, quality or safety standards; it is unreliable; it is unserviceable; is beyond economic repair; is the subject of a safety notice; etc.).
   - redundant equipment - (surplus due to, for example: changes in volume or nature of clinical services that it supports; a planned equipment replacement programme; etc.).

4. The process for general medical equipment disposal is shown in flowchart 5 below. Preparation from disposal shall include:

   - Decontamination
   - Contacting Clinical Engineering or associated equipment experts to ensure any contractual arrangements for the equipment is cancelled.
   - Removing any non-rechargeable batteries

- Removing all labels that identify the equipment as belonging to UHL
- Erasing any stored patient identifiable data in accordance with Information Governance policy.

5. Decommissioning of larger fixed installation equipment shall require project management by estates and facilities. Decommissioning of devices incorporating radioactive sources must be carried out in accordance with the Ionising Radiation Regulations 2017. Consult Clinical Engineering for any equipment that contains radioactive sources.

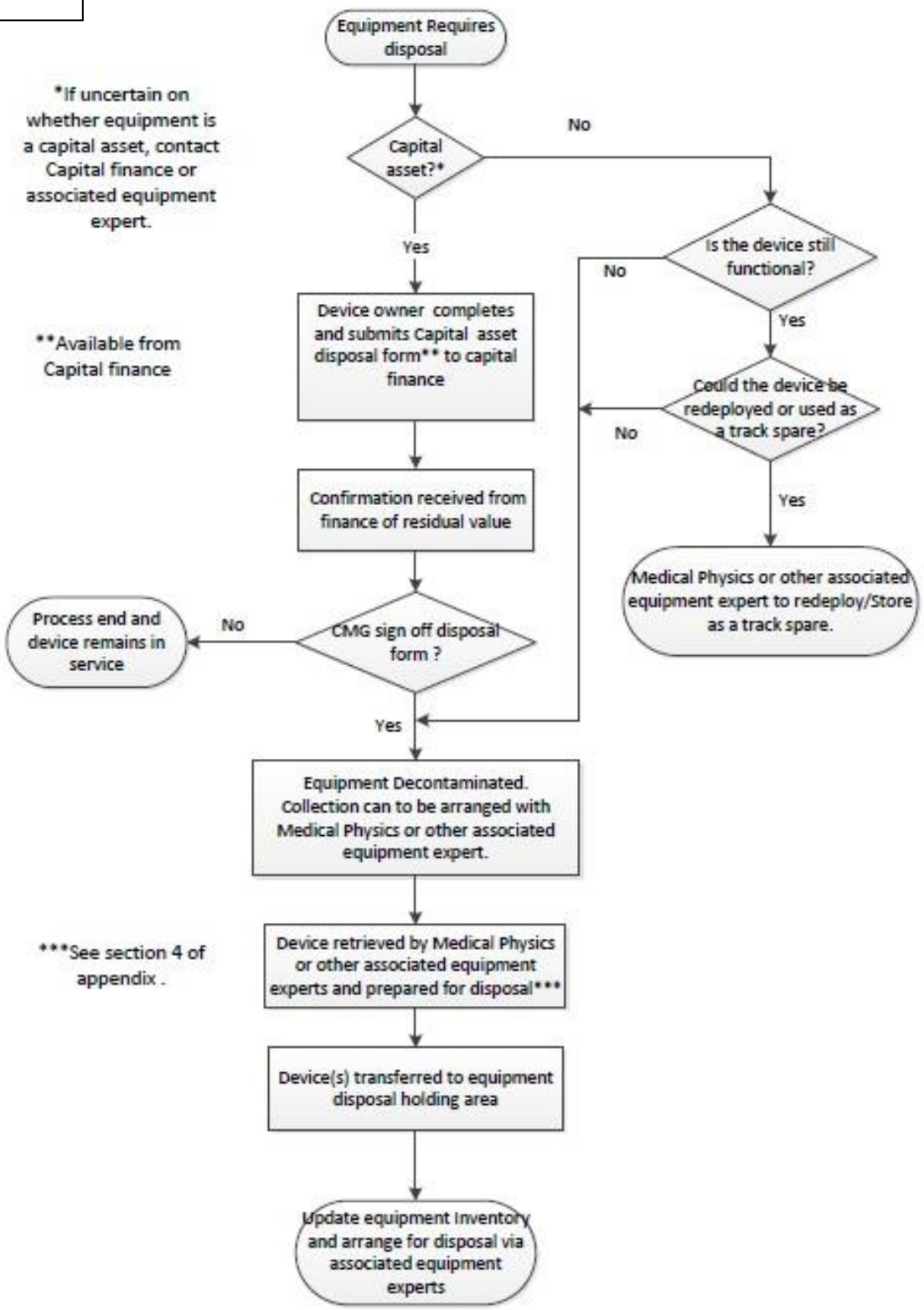
6. Decommissioning of equipment that has been used on infected patients shall require notification to Infection Prevention and may require incineration.

7. Clinical Engineering or other associated equipment expert (table 1) must ensure that applicable legal requirements are met, whichever disposal route is adopted, and that inventory records, including the Capital Finance Register are updated accordingly. The most appropriate way to ensure all Liability issues are addressed is by using an accredited auction house as a broker to re-sell assets, on behalf of the Trust. Clinical Engineering can advise on how to do this.

8. If equipment owners have a desire to donate equipment to specific charities, advice can be sought from the Director of Legal Affairs and/or Clinical Engineering as per Policy for the Donation and Loan of Equipment – B19/2004

9. Where Capital Equipment is replaced through MEE, CMG's may request to keep equipment for purposes such as training or research, on approval from the chair of MEE. If requests are approved, the replaced asset MUST NOT be used for routine clinical service. Capital Asset finance disposal forms should not be completed until the asset is removed from site.

Flowchart 5


Equipment Requires disposal
*If uncertain on whether equipment is a capital asset, contact Capital finance or associated equipment expert.
Capital asset?*
No
Yes
Is the device still functional?
No
Yes
Device owner completes and submits Capital asset disposal form** to capital finance
**Available from Capital finance
Could the device be redeployed or used as a track spare?
No
Yes
Confirmation received from finance of residual value
Medical Physics or other associated equipment expert to redeploy/Store as a track spare.
Process end and device remains in service
No
CMG sign off disposal form ?
Yes
Equipment Decontaminated. Collection can to be arranged with Medical Physics or other associated equipment expert.
***See section 4 of appendix .
Device retrieved by Medical Physics or other associated equipment experts and prepared for disposal***
Device(s) transferred to equipment disposal holding area
Update equipment Inventory and arrange for disposal via associated equipment experts

Appendix 9 – Maintenance Risk Assessment of Medical Devices

1. The risk assessment of Medical Devices owned by the Trust will be undertaken by Clinical Engineering or other associated equipment expert (table 1). This process will ensure consistency in the risk score applied to Medical Devices used across the Trust. Risk assessments will be conducted using the process within chapter 4 of IPEM report 95 - – Risk Management and its application to Medical Device Management) or another appropriate regime and the outcome of these assessments held on eQuip database.

2. The basis of the risk assessment will be whether or not the Medical Device is likely to cause significant harm or injury to the patient if it is not appropriately maintained or if a decision is made not to service the equipment in line with original equipment manufacturers instructions by the associated equipment expert (table 1)

3. Where Medical Devices are identified by the service provider as medium/high risk for maintenance needs; CMG's must ensure that they are maintained, by an appropriate maintenance agency, according to an agreed Planned Preventative Maintenance (PPM) schedule.

4. Clinical Engineering other associated equipment expert (table 1) will review PPM arrangements separately for all medical equipment that it manages on an ongoing basis and will inform CMG's of any assets that are not appropriately covered by a suitable PPM process. Clinical Engineering or other associated equipment expert (table 1) will also offer CMG's advice on what PPM arrangements need to be put in place to comply with this policy.

5. UHL Medical device maintenance service agencies shall report shortfalls in PPM arrangements to the Medical Equipment Executive who may request action plans from CMG's to address shortfalls in PPM cover. Where plans are not produced or are not fulfilled, within a 3-month period, the Medical Equipment Executive will refer the matter to Patient Safety Committee.

Appendix 10 – In-house manufactured Medical Devices, or devices to be used in clinical investigations or for trial purposes.

1. Manufacture and Modification of Medical Devices

1.1 Medical devices which are manufactured or modified within the Trust, for use within the Trust (IHMU), do not need to be CE/UKCA marked for compliance with the Medical Devices Regulations, but should meet the same safety standards. This applies also to the use of any CE/UKCA marked device for purposes not intended by the manufacturer (off-label use). Before use, a risk assessment should be completed and all such devices must be inspected and tested by the Clinical Engineering Department and their use authorized by the Head of Clinical Engineering, Clinical Engineering, or delegated individual. It is advisable to consult the Clinical Engineering Department at an early stage in the development or modification of such devices.

2. Clinical Trials involving Medical Devices

2.1 The Department of Health guidance for R&D outlines that all organisations providing care must be aware of all research that it is hosting, or any research activity involving participants, organs, tissue or data, which is obtained through that organisation.

2.2 All projects which involve NHS staff, patients, patient samples, patient records or facilities should be registered with the Trust's R&I Office and require approval from both the Trust and the relevant Research Ethics Committee (REC). Contact the UHL R&I Office for further guidance.

2.3 These requirements apply to trials involving the use of CE marked Medical Devices. In addition to the above requirements, clinical trials of non-CE marked, or off-label use Medical Devices supplied by an external organisation, e.g. a device manufacturer, must be registered with the MHRA in most cases.

2.4 Non-CE/UKCA marked or off-label use Medical Devices used for clinical trials must be inspected and tested by the Clinical Engineering Department and their use authorized by the Head of Clinical Engineering, Clinical Engineering, or delegated individual.

2.5 All reusable Medical Devices supplied for use in trials must be registered with the Clinical Engineering Department, who will undertake acceptance and safety testing of the devices where applicable.

2.6 For more information about what to do if you would like to use medical equipment for research purposes, please refer to Guideline for the Management of Medical Devices for Research and Development - B19/2013

3. Loan of CE/UKCA marked Medical Devices to UHL

3.1 Medical Device maybe loaned to the Trust for a variety of reasons:

- Part of a consumable deal
- Due to equipment failure
- Clinical Evaluation
- For a specific clinical requirement

- Research/Study

3.2 Trust staff arranging the loan of medical equipment must ensure that the Trust is indemnified against injury or damage caused by its use, and that the equipment is safe to use.

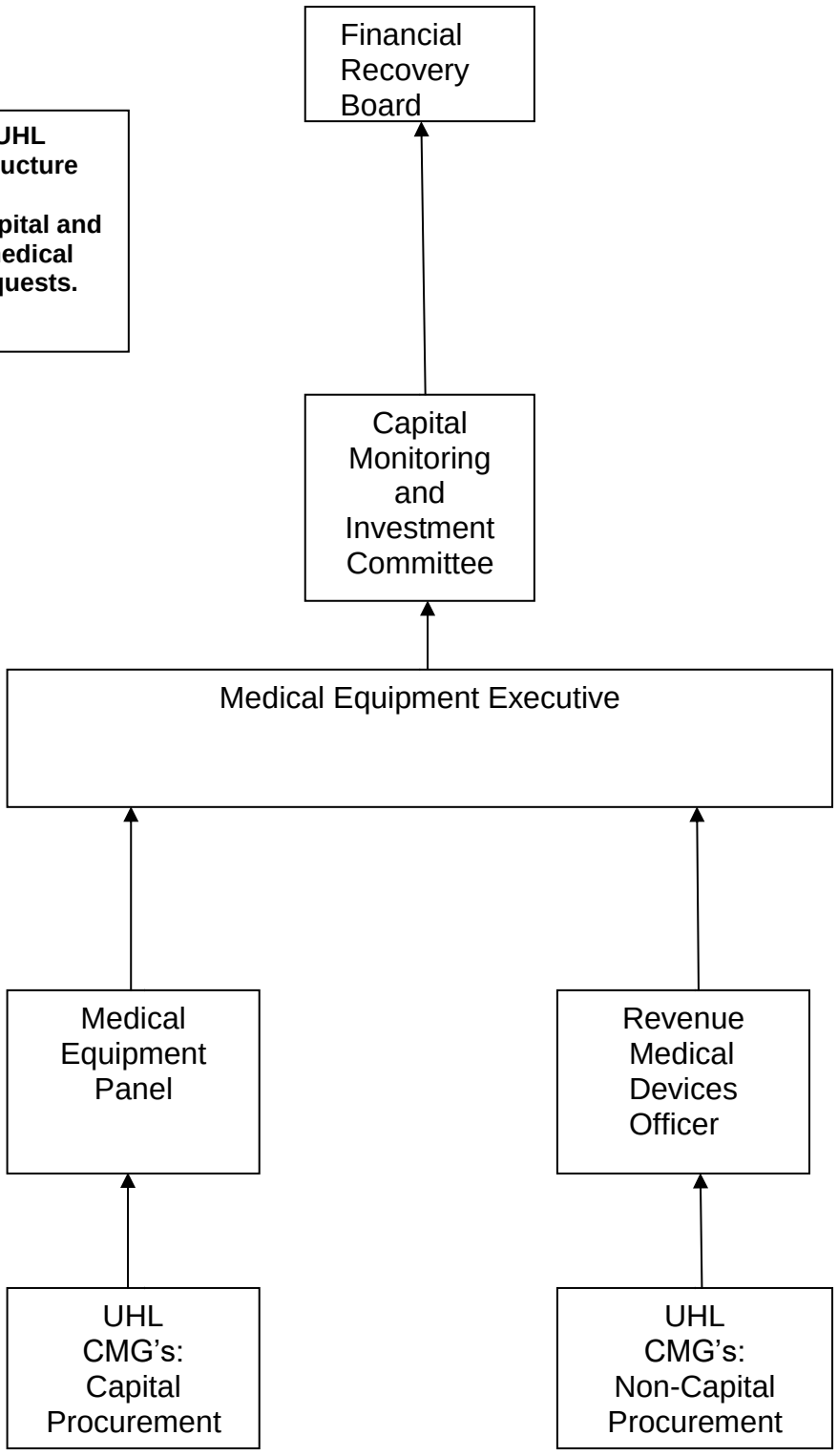
3.3 All suppliers loaning equipment to the Trust should be listed on the national MIA register. Loan equipment cannot be accepted unless the supplier is listed with an in-date indemnity status.

3.4 Before loan equipment can be used, the supplier must sign an MIA call-off agreement form (for each individual loan episode and item of equipment). All loan equipment must be acceptance tested as per section 3 of Appendix 3.

3.5 For more information about what to do if you would like to use loan medical equipment, please refer to Policy for the Donation and Loan of Equipment – B19/2004

Appendix 11 – UHL Medical Device Committee and Reporting Structure:

Flowchart 6 - UHL Committee structure for managing/ prioritising capital and non- capital medical equipment requests.



Flowchart 7 - UHL Medical Equipment reporting and Governance structure