University Hospitals of Leicester NHS
NHS Trust

Policy for the Management of Medical Devices for Research and Development

Approved By:	Policy and Guideline Committee
Date of Original Approval:	**15th April 2016**
Trust Reference:	**B19/2013**
Version:	V4
Supersedes:	V3 – July 2019
Trust Lead:	Jasdip Mangat, Clinical Scientist
Board Director Lead:	Andrew Furlong, Medical Director
Date of Latest Approval	12 August 2022 – Policy and Guideline Committee
Next Review Date:	**March 2026**

CONTENTS

REVIEW DATES AND DETAILS OF CHANGES MADE DURING THE REVIEW

V1 - Replaced MPEMS with Clinical Engineering throughout
Responsibility altered – inform Principal Investigator in place of R&D office

V2 - All medical devices to be sent to Clinical Engineering workshops – now to include non-electrical as well as electrical devices
Clinical Trials – changed from' must be registered' to 'may need to be registered'
Updated WEEE regulations to current version (2013)
Removed reference to euhl medical devices training and to Medical Devices Training Portal
Clinical Engineering monitoring KPIs added

V3 – Modifications to section on loan and indemnity of research equipment
Update of Appendix 1
Change for guideline to Policy

V4 - Update clause 4.2b to include correct references to document requirements. Update all sections referring to radiation and the Leicester Radiation Safety Service. Include contact details for R&I office.

KEY WORDS

Medical Device, Research and Development, CE Marked, Off Label Equipment, Indemnity

1 INTRODUCTION AND OVERVIEW

1.1 This document sets out the University Hospitals of Leicester (UHL) NHS Trust Policy for the management of medical devices and associated accessories intended for use in research activities (see flow diagram appendix 1).

1.2 The policy covers equipment that is purchased, loaned or donated. The procedure policy differentiates between CE marked and non CE marked devices or CE marked devices being used for purposes not intended by the manufacturer (off label). Comprehensive details for the management of equipment can be found in the UHL University Hospitals of Leicester (UHL) Medical Devices Policy (B26/2005).

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

2.1 This policy applies to all staff who intend to use medical devices within the UHL associated with research activities that are purchased, loaned or donated to the UHL or external organisations using medical devices on UHL premises.

3 DEFINITIONS AND ABBREVIATIONS

Definitions:

A **medical device** is defined under EU Regulation 2017/745 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.

Abbreviations:

UHL – University Hospitals of Leicester

MHRA - Medicines and Healthcare product Regulatory Authority

R&I – Research and Innovation

PPM – Planned Preventative Maintenance

IRAS – Integrated Research Application System

MPE – Medical Physics Expert

ARSAC – Administration of Radioactive substances Advisory Committee.

4 ROLES

4.1 The **Executive Lead** for this policy is the Medical Director.

4.2 Chief or Principal Investigator:

a) To make contact with Clinical Engineering and to ensure that equipment is inspected and tested before use and notify the Research and Innovation (R&I) Office of its status.

b) To ensure that all of the documentation outlined in points 5.2 and 5.3 are provided to Clinical Engineering with the equipment.

c) To arrange for any periodical maintenance of the equipment in accordance with the manufacturer recommendations or risk based maintenance strategies.

d) In the case of equipment that produces Ionising Radiation or for Non-Ionising Imaging, parts a) & b) will need to include Leicester Radiation Safety Service being informed & part of the process.

4.3 Clinical Engineer:

a) To ensure that all documentation supplied by the Principal Investigator is complete.

b) To perform acceptance and safety testing

c) To promptly inform the Principal Investigator when the device has passed all commissioning tests

4.3 Leicester Radiation Safety Service:

a) To ensure appropriate testing of all radiation equipment (both Ionising & Non-Ionising equipment) prior to use on patients.

b) To promptly inform the Principal Investigator when the device has passed all Acceptance & Commissioning tests.

c) Advise the Principal Investigator on the legislative requirements that need to be complied with to use the equipment.

5. POLICY IMPLEMENTATION AND ASSOCIATED DOCUMENTS

5.1 Equipment Acquisition

For equipment to be purchased, please refer to the UHL Medical Devices Policy (B26/2005) for the management and safe use of medical devices within the UHL. The policy details what is normally expected of equipment when acquiring it to be used within the Trust.

a) For equipment that is loaned or donated, loan agreements must be provided to clinical engineering on request. Loan agreements should cover aspects of indemnity, and responsibilities for repair and maintenance whilst on site and also ownership on completion of the study.

Please note, equipment loaned to the trust for the purposes of a research study are not governed by the MIA Call agreement system. Research projects in the

NHS in England are expected to have appropriate agreements in place that would cover insurance and indemnity arrangements for any loaned and/or gifted equipment

b) For equipment loaned as part of a commercially sponsored clinical trial, a clinical trial agreement must be in place. Appropriate indemnity will be confirmed by the UHL R&I Office in consultation with Clinical Engineering.

5.2 Acceptance of CE Marked Medical Devices

a) All medical devices must be sent to the local Clinical Engineering workshops for inspection, testing and registration on the equipment management database if appropriate. Where it is impractical to send the equipment to Clinical Engineering, the above task can be completed in the user department
– but it is the responsibility of the receiver to inform Clinical Engineering that they are required to test the equipment.

b) The equipment must be accompanied by:

- Statement that equipment is CE marked and is to be used as intended by the manufacturer.
- The study (EDGE Research database) reference number.
- Expected end date of study.

5.3 Non CE Marked Medical Device or Off Label Use

a) Clinical trials of such equipment may need to be registered with a competent authority (Medicines and Healthcare product Regulatory Authority (MHRA) in the UK). Evidence of registration must be submitted to the R&I Office. Clinical Engineering can advise on what equipment requires registration, although this will also be assessed during ethical approval stage.

b) The equipment and supporting documentation must be directed to the Clinical Engineering Lead Scientists or their Deputy for assessment. A risk assessment in accordance with the requirements within the BS EN 14971 Medical Devices Standard will also need to be carried out prior to use and acceptance. This assessment must be approved by the Clinical Engineering Lead Scientists or their Deputy and a manager from the department in which the equipment is to be used. Equipment deemed suitable and safe for the purpose of the study will then be forwarded to the appropriate Clinical Engineering workshop for inspection and testing.

5.4 Maintenance and Calibration

a) Medical devices identified as high risk must receive scheduled Planned Preventative Maintenance (PPM) to include calibration as necessary.

b) At a minimum all moderate and low risk medical devices will be electrically safety tested and calibrated as necessary.

5.5 Equipment that Generates or uses Ionising Radiation (x-rays etc.)

a) For equipment that generates or uses ionising radiation, the advice of the

Trust's Radiation Protection Adviser must be sought prior to the equipment coming onto the premises by contacting LRSS. A radiation risk assessment will need to be carried out prior to its use. This assessment must be completed by a person trained in risk assessment on behalf of the Trust and signed by a manager from the department in which the equipment is to be used and reviewed by the Trust's Radiation Protection Adviser.

b) No equipment containing radioactive materials, nor any radioactive sources is to be brought onto the premises without prior consultation with the Trust's Radiation Protection Adviser.

5.6 Equipment that generates visible and invisible Optical Radiation

a) Such equipment includes lasers and ultraviolet light sources

b) The supplier must be asked to provide an assessment of the luminant or illuminant output of the optical source together with its spectrum.

c) Leicester Radiation Safety Service must be informed to assist in undertaking a risk assessment and to ensure compliance with the requirements of The Control of Artificial Optical Radiation at Work Regulations 2010. The final risk assessment must be produced by the principal investigator and signed by the Laser Protection Adviser and a manager from the department in which the equipment is to be used.

d) All class 3 or 4 lasers must be subject to service agreements.

5.7 Equipment that generates high intensity Electro Magnetic Fields

a) The manufacturer must be asked to demonstrate compliance with The Control of Electromagnetic Fields at Work Regulations 2016. A risk assessment covering the use of the equipment should be completed by the Principal Investigator.

5.8 Equipment that uses ultrasound

a) Leicester Radiation Safety Service must be informed of all trial ultrasound equipment that comes onto site to ensure adequate testing prior to first use.

5.9 Equipment Disposal

a) All waste electrical and electronic equipment must be disposed of in accordance with the requirements of the Waste Electrical and Electronic Equipment Regulations (2013). Equipment owners should contact Clinical Engineering to arrange for the disposal of medical devices. This will ensure that the required disposal procedures are followed and database and Finance Department capital asset records updated. Disposal of waste radiation equipment must be undertaken following advice from the Trust's Radiation Protection Adviser.

b) Loaned equipment must be returned to the supplier. Clinical Engineering must be informed of all equipment returns to ensure assets are removed from the medical equipment database.

c) Loaned equipment that is to be retained by the Trust at the end of a trial will require the completion of a Medical Equipment Donation Form (B19/2004)).

5.10 Contacts

Clinical Engineering:

GH x13511 LRI

x15117 LGH x14657

Leicester Radiation Safety Service (LRSS), including the Radiation Protection Advisor

All sites call LRI x15978

or email mailbox at lrss@uhl-tr.nhs.uk

R&I Office

All sites call 0116 258 8351

Or email mailbox at RIAdmin@uhl-tr.nhs.uk

R&I Contracts

Email mailbox at RIContracts@uhl-tr.nhs.uk

6 EDUCATION AND TRAINING REQUIREMENTS

a) For medical devices which are identified as high risk, user training needs must be identified and training undertaken as necessary with records kept.

b) Medical devices assessed as low or medium risk, may not require formal, device specific training. However, individuals must keep their own records of all training on medical devices.

c) Training on radiation equipment needs to comply with various regulations. LRSS must be contacted for guidance on training requirements.

7 PROCESS FOR MONITORING COMPLIANCE

Element to be monitored	Lead	Tool	Frequency	Reporting arrangements Who or what committee will the completed report go to.
Incidents in relation to medical equipment used in research studies	Head of Clinical Engineering	Datix	Monthly	Medical Device Safety Officer Meeting

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.

9 SUPPORTING REFERENCES, EVIDENCE BASE AND RELATED POLICIES

UHL Medical Devices Policy (Trust ref B26/2005).

UHL Policy for the Donation and Loan of Equipment (Trust ref B19/2004).

The Control of Artificial Optical Radiation at Work Regulations 2010.

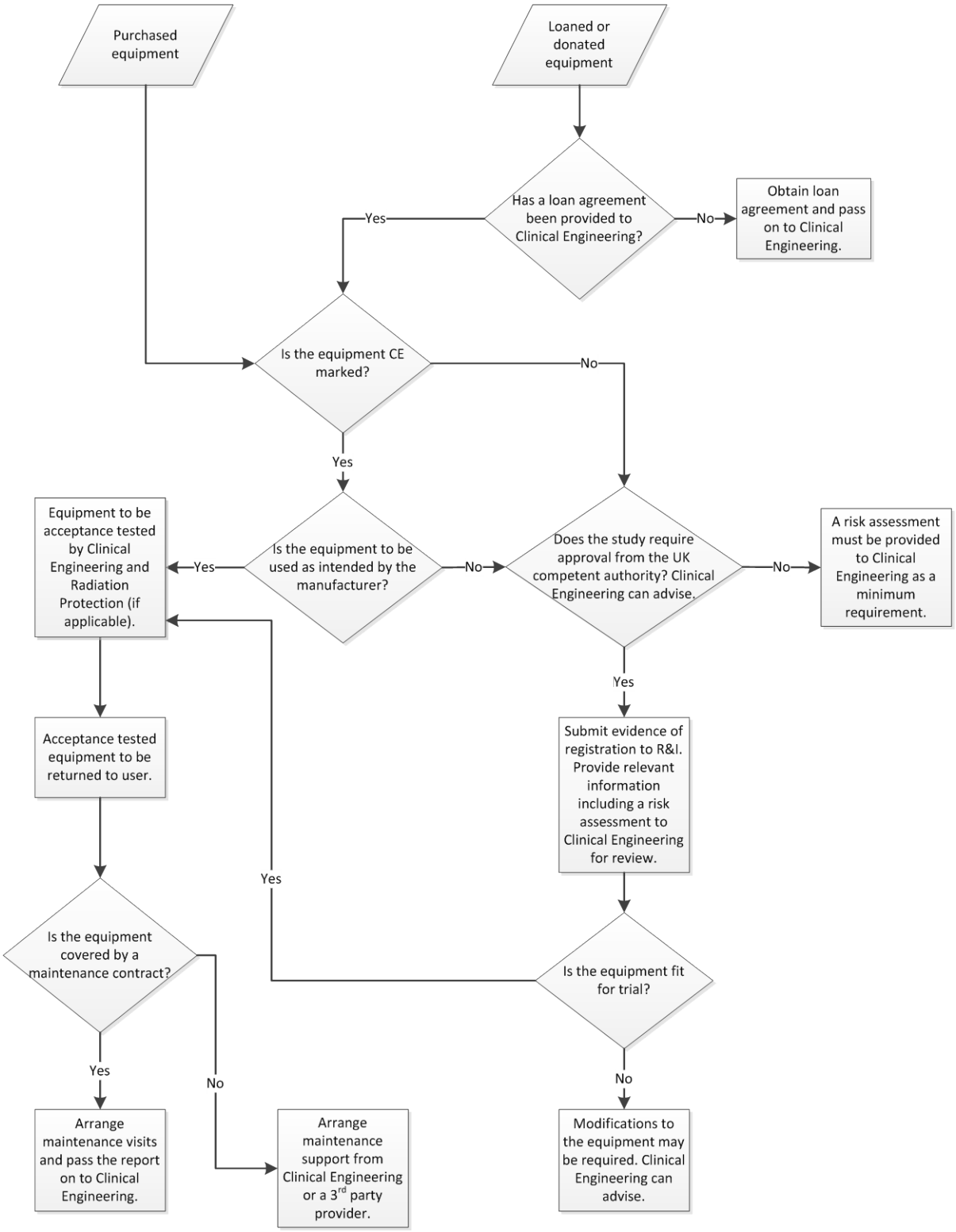
The Waste Electrical and Electronic Equipment Regulations (2013)

BS EN 14971 Medical devices. Application of Risk Management to Medical Devices

10 PROCESS FOR VERSION CONTROL, DOCUMENT ARCHIVING AND REVIEW

10.1 The updated version of the Policy will be uploaded and available through INsite Documents and the Trust's externally-accessible Freedom of Information publication scheme. It will archived through the Trust's SharePoint system

10.2 This Policy will be reviewed every three years or sooner in response to clinical risks/incidents identified.


Purchased equipment
Loaned or donated equipment
Has a loan agreement been provided to Clinical Engineering?
Yes
No
Obtain loan agreement and pass on to Clinical Engineering.
Is the equipment CE marked?
No
Yes
Equipment to be acceptance tested by Clinical Engineering and Radiation Protection (if applicable).
Yes
Is the equipment to be used as intended by the manufacturer?
No
Does the study require approval from the UK competent authority? Clinical Engineering can advise.
No
A risk assessment must be provided to Clinical Engineering as a minimum requirement.
Yes
Acceptance tested equipment to be returned to user.
Submit evidence of registration to R&I. Provide relevant information including a risk assessment to Clinical Engineering for review.
Yes
Is the equipment covered by a maintenance contract?
Is the equipment fit for trial?
Yes
No
No
Arrange maintenance visits and pass the report on to Clinical Engineering.
Arrange maintenance support from Clinical Engineering or a 3rd party provider.
Modifications to the equipment may be required. Clinical Engineering can advise.