# Policy Document

**Reference: MDM03**

University Hospitals of North Midlands NHS Trust

# Managing Medical Device Development, Modification & Trials

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| **Policy Author:** | **Head of Clinical Technology** |
| **Executive Lead:** | **Medical Director** |

## Version Control Schedule

| Version | Issue Date | Comments |
|---|---|---|
| 1 | October 2004 | |
| 2 | July 2008 | |
| 3 | November 2013 | |
| 4 | January 2016 | |
| 5 | May 2019 | References to UHNS removed. No other major updates. |

## Statement on Trust Policies

The latest version of 'Statement on Trust Policies' applies to this policy and can be accessed here

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## 1. INTRODUCTION

**1.1** This policy explains the implications of the Medical Devices Directive concerning **the development, modification and conduct of clinical investigations or trials using these devices in NHS Hospitals**. **It also covers any in-vitro diagnostic medical devices (IVDD).** The procedures described in this policy are mandatory and aimed at facilitating safe practice and to support innovations. The implementation of these guidelines will assist the University Hospital of North Staffordshire Trust (UHNM) to better assess and reduce risks involving such devices and to support developers.

**1.2** This policy should be read in conjunction with:

**Some of the relevant standards and references:**

- Medical Devices Directive (applies to CE marking requirements and use)
- BS EN 60601-1, Medical Electrical Equipment
- BS EN ISO 14971:20018, Medical devices- Application of risk management to medical devices.
- BS EN 540 , Clinical Investigation for human subjects
- Other relevant standards may be found on the web: www.bsi-global.com
- CE class classifications: www.medical-devices.gov.uk/MHRAwebsite2.nsf/webvwRegulatoryPublications
- www.medicines.mhra.gov.uk/inforesources/infolicapps/licappforms/maimpapp.doc
- www.devices.mhra.gov.uk/mda/mdawebsitev2.nsf

**In addition, the following documents provide useful guidelines**:

- Medical Device Regulations (No 8, No 9, Bulletin 18A)
- Application of the Medical Device Directive- Guidance notes. IPEM report No.74
- Medicines and Healthcare products Regulatory Agency (MHRA) guidance notes on clinical investigations
- ISO13485:2003 Quality Management System
- DB9801 Medical device and equipment management for hospital and community based organisations (MHRA).
- SA Spencer, S Nicklin, Y Wickramasinghe, A Nevill and SJ Ellis. An essential “health check” for medical devices. Clinical Medicine 2003;3:543-5
- Medical Device Alert MDA/2004/006 (issued 2-02-04)
- Risk analysis of medical devices- form: www.partnersinpaediatrics.org.uk see papers and reports/other reports

**Related Trust policies**

- Trust Policy RM07 - The Management of Incidents Including the Management of Serious Untoward Incidents
- Trust Policy C43- Trust Policy for Obtaining Consent
- Trust Policy G03 - Intellectual property
- Trust Policy G02 – Policy on Research Governance.
- Trust Policy C30 – Using New interventional Procedures or Undertaking Major Modifications to Existing Techniques.
- Trust Policy RM01 – Risk Management and Assurance policy and Strategy

## 2. POLICY STATEMENT

All medical device developments, modifications and trials are conducted in accordance with relevant legislation and guidance, and all medical devices produced by the organisation meet relevant regulatory requirements and safety standards and are ‘fit for purpose’.

## 3. SCOPE

**3.1** This policy comes into effect when a clinical user identifies a need for modification, development or trial of a medical device (see section 6.6 for software development). It guides the user to a better understanding of the regulations and legislation and points them to the appropriate course of action.

**3.2** This policy applies to all personnel involved in developing an in-house medical device, modifying a medical device which is currently in use or running a trial using these devices.

**3.3** The document however is not relevant for user trials (see 6.4.1) of a CE (Conformity European) marked device to be used for its intended purpose, for which there are established procedures already in place.

## 4. DEFINITIONS

### 4.1 Medical Device

Any instrument, apparatus, appliance, material or other article used alone or in combination, including software necessary for its proper application 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 the physiological process;
- control of conception;

and which do not achieve its principle intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means (As per Medical Devices Directive). Also see section 6.3 (for modifications) and 6.6 (for software).

In-vitro diagnostic devices (IVDD) are also included in this category.

### 4.2 CE Mark

The CE mark is the declaration of conformity with the essential requirements for safety and performance set out by the Medical Devices Directive. They are categorised according to risk levels: **Class I (low risk), Class IIa and Class IIb (medium risk) and Class III (high risk)**- the requirements for compliance becomes more stringent with progression towards Class III (to get more information about CE classes, see section 1.2). The CE mark is usually displayed on the medical device and the manufacturer should state the class in the documents (Example- Pre Purchase Questionnaire, PPQ form).

Medical devices constructed or developed by departments of the Trust (with ISO9001 accreditation and complying with the requirements of this policy), for use on patients within the UHNM legal entity cannot legally carry a CE mark. For these devices the Medical Devices regulations do not apply (MDA Bulletin 18A, IPEM report No.74). Such devices must be identifiable by a label. Devices that are too small to attach a label will be marked and user must be informed. It is also important to note that these devices should not be used outside the UHNM legal entity (unless a CE mark has been obtained).

If however there are plans to use the device outside the UHNM legal entity or plans to commercialise the device it will need to comply with the Medical Devices Regulations (www.devices.mhra.gov.uk/mda/mdawebsitev2.nsf/ ).

### 4.3 Clinical Investigation

A clinical investigation is required:

- When there is a need to verify the safety and performance of a device.

- Where an existing device, either CE or non-CE marked, is proposed for a new purpose or function.
- Introducing a new concept of device into clinical practice or when a device incorporates materials previously untested in humans.
- In circumstances where an existing device is modified in such a way that it contains a novel feature or where the modification might significantly affect the clinical performance and/or safety of the device.

These clinical investigations or trials need to be registered in advance with the UHNM Research & Development Department, require approval from the Local Research Ethics Committee and the Quality and Safety Forum (see section 6.4, 6.5 and 6.6 for MHRA approval). For clinical trials or user trials involving CE marked devices see section 6.4.1.

### 4.4 NICE / Safety and Efficacy Register of New Interventional Procedures

If the purpose of a clinical investigation is to prove a new concept / procedure or for a specified clinical or research commitment, the clinician must ensure that the procedure is registered with the National Institute of Clinical Excellence (NICE). Full details are given in Trust Policy C30 – Trust Policy for Consultants Using New Techniques or Undertaking Major Modifications to Existing Techniques.

## 5. RESPONSIBILITIES

### 5.1 UHNM staff member initiating the development or modification of a medical device and/or planning to conduct a clinical trial using these devices.

The UHNM staff member is responsible for:

- Leading the project
- Obtaining all approvals (see appendix 3)
- Ensuring that a risk assessment is carried out (see section Trust Policy RM01)
- Presenting the project to the Quality and Safety Forum if required (see 5.1.6)
- Complying with Local Research Ethical Committee requirements (See flow chart in appendix 1)
- All development and modification of medical devices (external or in-house) must be brought to the attention of the Head of Clinical Technology, who will maintain a corporate register of such activities. Notification of any additions or updates to this register will be reported to the Medical Device Strategy Committee bi-annually under that committee's agenda, which Committee may request more details from the staff member leading the work.
- If the project lead thinks that there may be significant clinical risk issues in using this device advice must be sought from the Quality and Safety Forum before commencing any work or committing resources.
- All staff should ensure that they follow the requirements to be met in the development and modification of medical devices and conduct of clinical trials as outlined in **Appendix 2 – Further information and general Principles**.

### 5.2 Quality and Safety Forum

The Quality and Safety Forum is responsible for:

- Receipt and approval of applications from project leads, as required
- Receipt and approval of regular update reports, including endorsement of the central register for in-house developed or modified medical devices and trials using such devices
- Review of recommendations and assessments from risk assessment panels
- Approving the use of a device for routine clinical use within the UHNM legal entity
- To ensure that clinicians using such devices are aware of the need to inform patients, where appropriate

### 5.3 Risk Assessment Panel

- The Risk Assessment Panel is responsible for:
- Conducting comprehensive risk assessments
- Making recommendations to the Quality and Safety Forum
- Advising project leads

### 5.4 Risk assessors

- The principal risk assessor shall lead the process (the principal risk assessor will depend on the type of medical device and may be in any one of the following speciality areas, for example: Clinical Technology, Medical Physics, Radiotherapy, Audiology, Pathology, Sterile Services & Decontamination)
- The risk assessment is carried out by no less than three assessors
- The principal risk assessor would co-opt a specialist(s) onto the panel as required and /or initiate an external review if deemed necessary
- Contribution to the process as required

### 5.5 Head of Clinical Technology

Head of Clinical Technology is responsible for:

- Policy Lead, in conjunction with the Deputy Medical Director
- Ensuring that the Department maintains a central register of all newly developed or modified medical devices and any trials using these, which have been brought to their attention
- Ensuring that an update report is provided to the Medical Device Strategy Committee every 6 months.
- Where required, identifying risk assessors, allocating technical support
- Advising on compliance and current legislation issues, and providing guidance where required

### 5.6 Manager of Sterile Services and Decontamination Manager

Manager of sterile services and decontamination manager are responsible for:

- Advising on sterilisation and decontamination issues

### 5.7 External Supplier/Manufacturer (for non CE marked devices requiring a clinical investigation)

External suppliers / manufacturers are responsible for:

- Obtaining approval from the Medicines and Healthcare products Regulatory Agency (MHRA) for the clinical investigation
- Provision of suitable indemnity

## 6. MONITORING AND REVIEW ARRANGEMENTS

**6.1** This policy will be reviewed 3 years after issue, or earlier if required (e.g., following major change in legislation).

**6.2** All development and modification of medical devices (external or in-house) must be brought to the attention of the Head of Clinical Technology, who will maintain a corporate register of such activities. Notification of any additions or updates to this register will be reported to the Medical

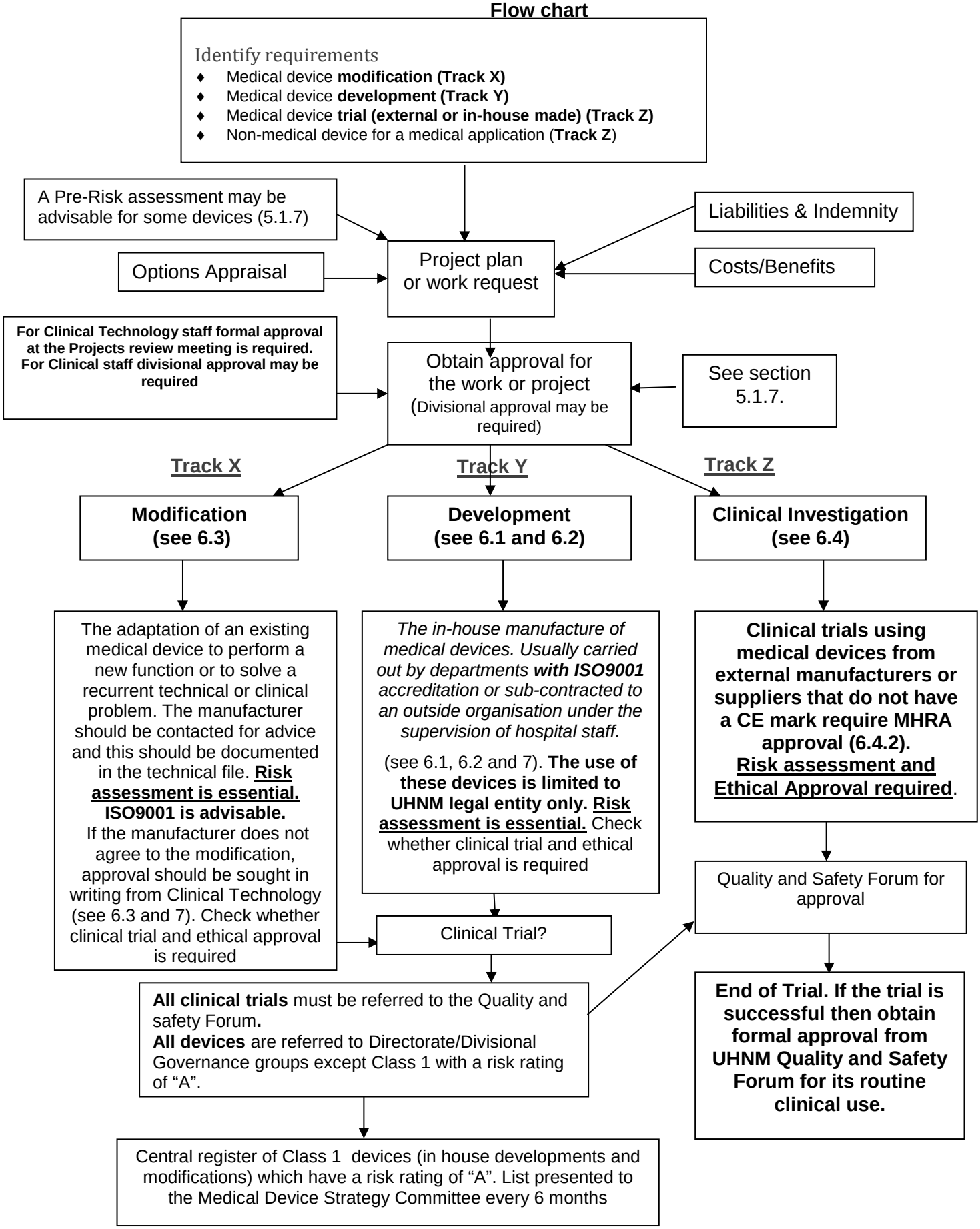
Device Strategy Committee bi-annually under that committee's agenda, which Committee may request more details from the staff member leading the work.

**6.3** The Quality and Safety Forum is responsible for receipt and approval of regular update reports, including endorsement of the central register for in-house developed or modified medical devices and trials using such devices.

**6.4** The Head of Clinical Technology is responsible for ensuring that an update report is provided to the Medical Device Strategy Committee every 6 months.

**APPENDIX 1**

## Flow chart



## APPENDIX 2: FURTHER INFORMATION AND GENERAL PRINCIPLES

### Requirements to be met in the development or modification of medical devices and conduct of clinical trials (also see Appendix 1)

**Medical devices developed before June 1998**

- Compliance with the Medial Devices Regulations has been required since June 1998. The Trust, through the Department of Clinical Technology, has had in place a risk assessment process since 1996. This risk assessment process is therefore available for use for any retrospective requirements.

- *Sections 6.2 and 6.3 apply to all current developments and modifications.*

- **Medical Device Development (in-house)**

  - If the lead thinks that there may be significant clinical risk issues in using this device advice must be sought from the Divisional Governance Group before commencing any work or committing resources.

  - The key person initiating and leading the in-house development of a medical device (see 5.1) must ensure that a risk analysis is carried out by the risk assessment panel. The principal risk assessor may co-opt an external specialist to the panel if required. All devices except those that can be categorised as CE class 1 and with a risk rating of "A" require **approval from the Quality and Safety Forum.** All devices requiring a clinical trial need approval from the Quality and Safety Forum.

  - Clinical trials involving in-house developed medical devices that are to be used on patients within the UHNM legal entity may not require formal approval from the MHRA.

  - Local ethical committee approval may be required.

  - Detailed requirements for in-house design are given in Appendix 2. The check list can be found at Appendix 3.

  - Upon completion of the project, the routine use of the medical device on patients, within the UHNM legal entity, can only be approved by the UHNM Quality and Safety Forum. Such devices should not be used in locations outside the UHNM legal entity.

  - If the device has commercial potential a relevant organisation to develop and market the product could be contacted by the persons involved in the design. It is usual for the commercial organisation to apply for the CE mark for the stated purpose. Intellectual property rights (IPR) and patent issues must be negotiated according to the UHNM Trust policy (G03).

  - Post production requirements: procedures should be in place for planned maintenance and recall of the device.

**Medical Device Modification (in-house)**

- If the lead thinks that there may be significant clinical risk issues in using this device advice must be sought from the Quality and Safety Forum before commencing any work or committing resources .

- Requirements are as for development of medical devices and a risk assessment is required. All devices except CE class 1 and with a risk rating of "A" require approval from the Quality and Safety Forum. All devices requiring a clinical trial need approval from the Quality and Safety Forum. (The risk assessors may decide not to enforce some of the requirements depending on the extent of the modification).

- Attachment of interfaces (with or without software) to the output (s) of medical devices that are not specified by the manufacturer is also considered a modification of the medical device and manufacturer's written approval must be obtained. In some instances this interface could become a medical device in its own right (see section 6.6).

- Before starting on any modification, a formal assessment of options and liabilities must be taken (see flow diagram in appendix 1). In the event the manufacturer or the supplier of the original medical device considers the modification to be an infringement of the CE mark, then the project lead should inform the risk assessment panel, and seek advice on whether to continue with the modification, continue to use with restrictions or withdraw the medical device from use.

- Carrying out the modification may transfer risk and liabilities to the Trust, which should be assessed carefully. (see checklist in Appendix 3).

**Clinical Trials or "User Trials" Using Medical Devices from External Manufacturers/Suppliers**

- **For CE marked medical devices**

  - Usually referred to as "user trials" to evaluate the most appropriate medical device (e.g., prior to purchase). There are already well established procedures in place for this (contact Clinical Technology for further information).

  - **For non-CE marked medical devices or those used outside the intended purpose:**

- For clinical investigations, the Secretary of State must be notified through the MHRA using their PCA1 and PCA2 forms at least 60 days prior to the commencement of the trial. This requires full details of the medical device and the investigation (i.e. number of patients, selection criteria, local ethical committee approval, data collection methods and analysis).

- It is the responsibility of the manufacturer to ensure that the MHRA is informed and approval is received. (www.medicines.mhra.gov.uk/inforesources/infolicapps/licappforms/maimpapp.doc).

- Clinical Technology must be informed so that the trial can be added to the central register

- Approval from the Quality and Safety Forum is required

- The MHRA make a charge for registering a clinical investigation (Information with Clinical Technology Department)

- **At the present time clinical trials involving medical devices constructed or developed or modified by UHNM departments do not require MHRA approval for use on patients within UHNM legal entity. It is advisable for those departments to have a suitable accreditation such as ISO9001.**

Use of a Device which is not covered by the Medical Device Directive (as a medical device), for a Medical Application

There are various devices in the market which are CE marked but not defined as a medical device. Any person intending to use such a device for a medical application (see section 4.1 for definition) within the UHNM legal entity, must treat it under section 6.4.2 as a non-CE marked medical device and work in collaboration with the manufacturer of the device. MHRA approval may be required and Track Z in the flow chart in Appendix 1 applies. Local ethical committee approval may be required. Approval from Quality and Safety Forum is required. Use limited to UHNM legal entity only.

**Development of software for use in conjunction with a medical device**

- The MHRA considers that software developed for enhancing the operation of a medical device is also a medical device in its own right. Further, software that is used to bring together data to assist in making a diagnosis is also considered a medical device.

- This policy therefore is applicable to these circumstances as well.

**In-vitro Diagnostic Devices (IVDD)**

All IVD devices should now carry a CE mark and the directive applies not only to devices which are placed on the market, but also to which are used in the context of "professional activity".

However this directive will not apply to IVDDs manufactured and used within the same legal entity (same health institution). Such devices made within the UHNM should not be used outside this legal entity.

**Acceptance Test and Risk Analysis**

- The Clinical Technology department has ISO9001 accreditation. For in-house developed or modified medical devices, an engineer separate from the design group will carry out a compliance test, which includes the electrical safety test and inspection. Risk analysis is more comprehensive and will identify any training issues, the need for any warning labels, user instructions and safety issues among other things. The acceptance test is carried out on all medical devices. This should identify any potential safety concerns. It is advisable for all departments involved in developments and modifications to have a suitable accreditation such as ISO9001

- For in-house developed medical devices the risk assessment panel will decide whether a report from an external specialist or a thorough inspection and testing by an external test house is required (eg. to EN 60601-1). This depends on the CE class and the risk level. It is likely that Class IIa, IIb & Class III devices may require these and the medical device may be sent to an external test house for an independent test report. This will incur additional substantive costs and must be considered at the time the work is considered or project plan is written.

**Issues on sterilisation and decontamination**

The Manager of HSDU must be consulted regarding sterilisation of devices and any decontamination issue referred to the UHNM Decontamination Manager (see risk analysis form). Medical devices developed or modified in-house by a department that has the ISO 9001 accreditation may be reprocessed at the UHNM HSDU, for use on patients within the UHNM legal entity. These should not be used at locations outside the UHNM legal entity. Other departments should contact the HSDU for advice.

**APPENDIX 3**

## Technical file

**The following information is required for <u>in-house</u> designed, constructed or modified medical devices (ISO9001 accreditation advisable):**

**<u>Technical files</u>** are aimed for skilled personnel who are not familiar with the device. Technical files should include the following:

- Project plan (if applicable).
- Description of the device and data sheets of its components.
- Specifications of the device.
- Design methods: including technical drawings, circuit diagrams, sub-assemblies and methods of manufacture.
- Any correspondences from the manufacturer. These might be in the form of letters, summary notes of phone calls, visits, etc. (essential in case of modifications).
- Results of risk analysis. Details of standards or alternative solutions must be provided.
- Methods of sterilisation and any decontamination (a note from the Manager of HSDU or Decontamination officer if applicable).
- Results of design calculations and test inspections.
- Connectability to other devices.
- Acceptance-test reports and clinical data (if applicable). These must give details of set-ups, procedures and results.
- Device labelling and instructions.
- Approval from UHNM Directorate/Divisional Governance Groups (if applicable).
- User manual

**<u>Medical devices made by external organisations:</u>**

**For newly introduced medical devices the manufacturer or supplier should be prepared to produce these to the UHNM if requested.**

- CE approval documentation (if CE marked)
- MHRA notification and their approval for clinical trial to go ahead (if not CE marked)
- Approval from a UK certified notified body regarding safety and compliance for use as a medical device.
- UHNM staff member involved with the use of the device should provide risk assessment details.

**APPENDIX 4**

## CHECK LIST FOR THE DEVELOPMENT OF A NEW OR MODIFICATION OF AN EXISTING MEDICAL DEVICE:

| | YES | NA |
|---|---|---|
| • Project Plan | ☐ | ☐ |
| • Technical file as detailed in appendix 2 | ☐ | ☐ |
| • User manual as detailed in appendix 2 | ☐ | ☐ |
| • Clinical risk analysis | ☐ | ☐ |
| • Acceptance test report by Clinical Technology | ☐ | ☐ |
| • Test house report | ☐ | ☐ |
| • Approval from the Quality and Safety Forum | ☐ | ☐ |
| • User training provided | ☐ | ☐ |
| • Ethical approval for clinical trials | ☐ | ☐ |

**For non-CE marked medical devices supported by a manufacturer the following is also required:**

- Completion of MHRA notification documentation, including the application forms PCA1 and PCA2 and provision of the appropriate supporting documentation.
- Approval from MHRA for the stated purpose.