Reference Number: UHB 223 **Version Number:** 4	**Date of Next Review:** 31st Mar 2022 **Previous Trust/LHB Reference Number:** N/A

In-house Adaption, Modification, Manufacture and Repair of Medical Equipment Procedure

Introduction and Aim

The Cardiff and Vale UHB Medical Equipment Management Policy covers the management of all medical equipment in use in the Cardiff and Vale University Health Board irrespective of the source of funding for the equipment.

The aim of this procedure is to provide clarity to those undertaking the management of medical equipment in order to ensure that the relevant legislation, standards, guidance and best practice are implemented, in particular, as set out in the Best-practice guidance for the in-house manufacture of medical devices and nonmedical devices, including software in both cases, for use within the same health institution (IPEM January 2021)[1].

Objectives

- To ensure Cardiff and Vale UHB complies with NHS Wales Health and Care Standard 2.9 Medical Devices, Equipment and Diagnostic Systems

Scope

This procedure applies to all of our staff in all locations including those with honorary contracts. It applies to all Medical Equipment used by Cardiff and Vale UHB services irrespective of whether the Medical Equipment is owned, loaned, leased or used by commissioned external service providers.

Equality Health Impact Assessment	An Equality Health Impact Assessment (EHIA) has not been completed as this procedure has been written to support the implementation the Cardiff and Vale UHB Medical Equipment Management Policy for which an assessment has been completed and found a positive impact.
Documents to read alongside this Procedure	Cardiff and Vale UHB Medical Equipment Management Policy
Approved by	Cardiff and Vale UHB Medical Equipment Group

Accountable Executive or Clinical Board Director	Executive Director of Therapies and Health Science
Author(s)	Head of Rehabilitation Engineering

Disclaimer

If the review date of this document has passed please ensure that the version you are using is the most up to date either by contacting the document author or the Governance Directorate.

Summary of reviews/amendments

Version Number	Date of Review Approved	Date Published	Summary of Amendments
1	01/04/2014	15/04/2014	New Document
2	20/10/2017	12/12/2017	Updated terminology and references
3	25/03/2020	15/03/2020	Update to take account of full implementation of MDR 2017 with effect from 26th May 2020 pending publication of relevant MHRA Guidance
4	17/03/2021	04/04/2021	Update to take account of the changes in legislation as a result of Brexit and publication of the Best-practice guidance for the in-house manufacture of medical devices and nonmedical devices, including software in both cases, for use within the same health institution (IPEM January 2021)

CONTENTS

1.0 BACKGROUND

The Cardiff and Vale UHB Medical Equipment Management Policy covers the management of all medical equipment in use in the Cardiff and Vale University Health Board irrespective of the source of funding for the equipment. The Policy describes management of medical equipment as encompassing a range of activities including its use and repair. The Policy also states that, for equipment manufactured or modified in-house, appropriate Technical Files must have been created and approved and all documentation and approvals must be comply with the recommendations of the Best-practice guidance for the in-house manufacture of medical devices and nonmedical devices, including software in both cases, for use within the same health institution (IPEM January 2021)[1].

The purpose of this procedure is to provide clarity to those undertaking the management of medical equipment in order to ensure that the relevant legislation, standards, guidance and best practice are implemented[1,2,3,4].

2.0 APPLICATION

This procedure is to be followed upon the in-house adaptation, modification, manufacture or repair of any medical equipment covered by the Policy including stand-alone software (or 'apps') that supports clinical decision making which is classified as a medical device and therefore falls under the Medical Devices Regulations (please see MHRA Guidance: Medical device stand-alone software including apps (including IVDMDs) - last updated 21 April 2017[2]).

3.0 RESPONSIBILITES, AUDIT AND REVIEW

The Executive Director of Therapies and Health Science is the Executive Director with responsibility for medical equipment.

The Medical Equipment Group is responsible for this procedure and will keep it under regular review.

The Clinical Engineering Department and Rehabilitation Engineering Unit will monitor and audit the application and implementation of the policy.

4.0 PROCEDURE

When undertaking the following:

1. Adaptation/modification/repair of a medical device or equipment as explicitly endorsed by the manufacturer (either via 'instructions for use' or a separate written agreement).

   This activity does not fall within the scope of IPEM January 2021[1]. A formal record of the adaptation/modification/repair must be made as part of the ongoing management of that medical device or equipment.

2. Modification/repair of a medical device or equipment not explicitly endorsed in writing by the manufacturer but which does not change the intended purpose of the medical device or equipment.

   As this activity may fall within the scope of IPEM January 2021[1] it will be considered to do so for the purposes of this Procedure (see below).

3. Modification of a medical device or equipment not explicitly endorsed in writing by the manufacturer which changes the intended purpose of the medical device.

   This activity falls within the scope of IPEM January 2021[1] (see below).

4. Research/design/development/manufacture of new medical devices or equipment.

   This activity falls within the scope of IPEM January 2021[1] (see below).

IPEM January 2021[1] recommends that an 'appropriate quality management' system (such as BS EN ISO 13485) be in place to assure the safety and effectiveness of medical devices put into service. For the purposes of this Procedure, activities 2, 3 and 4 above must be undertaken in line with the 'principles' of BS EN ISO 13485 (as demonstrated via documented processes although formal certification and external audit will not be required at this time) to ensure that their ongoing safety and effectiveness is regularly reviewed and remedial action taken as necessary. For the sake of clarification, those documented processes for undertaking activities 2, 3 and 4 above may already be covered by BS EN ISO 9001 certification or BS EN ISO 15189 accreditation in which case their content should be reviewed regularly by the local quality manager (or other nominated competent and senior person with equivalent responsibilities) to confirm that they continue to operate in line with the 'principles' of BS EN ISO 13485 for the purposes of this Procedure.

5. DEFINITION OF TERMS

Adaptation: Alteration or configuration, for example, in accordance with a prescription, but without making physical changes to the medical device or equipment.

Modification: Physical changes to an existing medical device or equipment.

6. REFERENCES

1. Best-practice guidance for the in-house manufacture of medical devices and nonmedical devices, including software in both cases, for use within the same health institution (IPEM January 2021)

2. MHRA Guidance: Medical device stand-alone software including apps (including IVDMDs) - last updated 21 April 2017

3. Managing Medical Devices (MHRA 2021)

4. Health and Care Standards (NHS Wales 2015)