Medical Devices Policy

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Record of Changes

Date	Version	Page	Amendment
04/03/2024	1		New document reviewed by Medical Devices Safety Group for potential recommendation for ratification
28/10/2024	1		Document ratified by Medical Devices Committee
11/02/2025	1.1		Updated group / committee name references (non-substantive changes) for clarity, following re-name to Medical Devices Committee / Medical Devices Safety Group

CONTENTS

1. Overview and Introduction

1.1 This policy governs the management of medical devices in Highland Health Board. Medical devices are used throughout healthcare systems to provide care. When used correctly they are key to provision of high quality care. When used incorrectly or in an unsafe condition, harm or incorrect diagnosis may result.

2. Scope

2.1 This Policy covers the management of medical devices in Highland Health Board, including medical equipment. It applies to *Medical Devices* as defined by the UK Medical Devices Regulations:

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

(a) is intended by the manufacturer to be used for human beings for the purpose of-

(i) diagnosis, prevention, monitoring, treatment or alleviation of disease,

(ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,

(iii) investigation, replacement or modification of the anatomy or of a physiological process, or

(iv) control of conception; and

(b) does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, even if it is assisted in its function by such means,

and includes devices intended to administer a medicinal product or which incorporate as an integral part a substance which, if used separately, would be a medicinal product and which is liable to act upon the body with action ancillary to that of the device

2.2 The definition of medical devices in regulation is also deemed to include products specifically intended for the cleaning, disinfection or sterilisation of devices.

2.3 The Policy will also apply to medical laboratory equipment, IT equipment and software including standalone software used for the above purposes.

2.4 It applies irrespective of how medical devices were acquired: whether purchased, used on trial, loaned, donated, rented, leased or obtained through any other mechanism.

2.5 This Policy and associated protocol and procedure applies to all staff delivering clinical services under Highland Health Board's governance, including those on fixed term or honorary contracts or temporary / bank arrangements.

3. Policy Objectives and Principles

3.1 Systems of management and control are required to ensure that risks associated with medical devices are minimised. There is a wide range of risks that need to be controlled including ensuring that devices are available and fit for purpose, properly maintained and correctly used.

3.2 Effective management of medical devices requires attention to both clinical and financial governance, to make best use of board resources in reducing risk and increasing clinical benefit.

3.3 The underlying principles of medical devices management will be those in Scottish Health Technical Note (SHTN) 00-04 “Guidance on Management of Medical Devices and Equipment in Scotland's Health and Social Care Services” and compliance with that standard will be treated as the overarching policy objective. This is in recognition government guidance is sufficiently detailed to be used as a straight-through statement of policy aims at health board level. It shall be an efficiency aim for board controlled documents associated with medical devices to focus on practical and transparent implementation, including recognised gaps for closure, rather than reproduction of widely accepted policy aims and best practice.

3.4 Management systems should also address relevant underlying legislation, guidelines and requirements, address recommendations for provision published by the Scottish Health Technologies Group (SHTG) and National Institute for Clinical Excellence (NICE) and be cost effective.

4. Delivery and Implementation

4.1 Highland Health Board will achieve the benefits for patients of medical device use and keep patients, staff and visitors safe through having systems to ensure that all risks associated with medical device acquisition and use of medical devices are as low as reasonably practicable.

4.2 Medical devices will be used and managed in accordance with the detail of associated protocols and procedures. In the initial version 1.1 of this policy this associated documentation is still to be produced and is included in a transitional workplan, is listed in Appendix A.

4.3 Approval of the associated procedural documentation is delegated by the Lead Executive as set out in Appendix A.

4.4 All staff should highlight any concerns about devices or device use at the earliest opportunity.

5. Roles and Responsibilities

5.1 The duties of staff and responsibilities of different groups under this Policy shall be defined in the associated protocols and procedures.

5.2 The Lead Executive for this policy is the nominated board level director with overall responsibility for medical device management.

5.3 The Lead Reviewer(s) of this Policy have the delegated authority to make non-substantive amendments with notification to the Lead Executive.

6. Monitoring Compliance and Effectiveness

6.1 Different areas of practice will be monitored as specified in associated protocols and procedures.

6.2 An audit programme of compliance with this policy and supporting documentation will be maintained by the Medical Devices Safety Group.

6.3 Overall assurance of compliance with this policy will be monitored by the Medical Devices Safety Group. The Medical Devices Safety Group shall report at least annually to Clinical Governance Committee on the audit programme of compliance or as otherwise required by exception.

7. Equality Impact Assessment (EQIA)

7.1 In the initial version 1.1 of this policy responsibility is delegated to groups listed in Appendix A and staff with roles and responsibilities under associated documentation, to consider EQIA when introducing and implementing procedures to comply with this policy.

7.2 In fulfilling responsibilities of this policy particular attention should be given to equality of provision including the recommendations referenced in clause 3.4 above.

8. Consultation Details and Communication Plan

Consultation:

Name/s of person or group	State which corporate services/staff groups the person or group represents	Date	Response: FU/FNU/NR
Medical Devices Safety Group	Board assurance group	04/03/2024	**FU**
Lead Executive Signoff	Exec Lead Signoff	28/10/2024	**FU**
Medical Devices Committee	Board governance committee	28/10/2024	**FU**

Key: *Feedback used / received and no suggested changes (FU), not used (FNU) or not received (NR)*.

Communication plan (to be triggered by any non-substantive amendment):

- Executive Directors
- Medical Directors
- Chief Officers
- Heads of Operations
- Head of Procurement
- Chair Health & Safety Committee
- Chair of Clinical Governance Committee
- Head of Medical Physics
- Head of Estates
- Head of Facilities Management
- Head of EHealth
- Radiation Policy Lead
- Research, Development & Innovation Manager

Plan above applies to this Policy only. Associated protocols and procedures will have their own proportionate and appropriate to scope.

9. References and Associated documents

Legislation, guidance and standards applicable to medical devices or associated as a wider theme includes a very wide range of publications.

In accordance with the stated policy objective of straight-through overarching compliance with SHTN) 00-04, the References section in that national guidance document will be treated as an appropriate list for the purposes of this policy.

1. National Services Scotland (NSS), June 2021. SHTN 00-04 Guidance on Management of Medical Devices and Equipment in Scotland's Health and Social Care Services. Available through: NSS Website.

14. Appendix A: Schedule of Associated Documentation and Delegation

Changes or additions to this schedule will be made in accordance with protocol for changes to the overall policy.

In this version 1.1 of this policy the list below is not exhaustive and representative of a transitional workplan for areas of protocol and procedure that are recognised as requiring documented.

Controlled Document	Reviewer / Owner Group(s)	Ratification Group	Status (at time of this Policy version)
Policy			
Medical Devices Policy (this document)	MDSG	MDC	New document
Protocol and Procedure			
Medical Equipment: Acquisition, Introduction or Procurement	MP	MDSG	*To be Authored – 2024* *Legacy version is within Policy for Medical Equipment, 2008.*
Loan Medical Equipment Policy	MP	MDSG	*2021 version*
Medical Equipment: Replacement and Disposal	MP	MDSG	*To be Authored – 2024* *Legacy version is within Policy for Medical Equipment, 2008.*
Medical Equipment Maintenance	MP	MDSG	*To be Authored – 2025* *Legacy version is within Policy for Medical Equipment, 2008.*
Patient-issued medical devices (Issue, Maintenance / Checks / Retrieval)	MDSG with Primary Care	MDSG	*To be Authored – 2025*

Novel, research, “in-house” or “modified” devices	MP with RD&I	MDSG	*To be Authored – 2025*

Key:
MP = Medical Physics
MDSG = Medical Devices Safety Group
MDC = Medical Devices Committee
RD&I = Research, Development and Innovation